

DRUG SAFETY AND PRICING

HEARING
OF THE
COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS
UNITED STATES SENATE
ONE HUNDRED SIXTH CONGRESS
SECOND SESSION

ON
EXAMINING THE ACCESSIBILITY OF AFFORDABLE PRESCRIPTION
DRUGS, THE PRICE DIFFERENTIALS FOR IDENTICAL PRESCRIPTION
DRUGS IN THE INTERNATIONAL MARKETPLACE, AND DRUG QUALITY
AND SAFETY

JUNE 13, 2000

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TUESDAY, JUNE 13, 2000

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10 o'clock a.m., in room SD-430, Dirksen Senate Office Building, Senator Jeffords (chairman of the committee) presiding.

Present: Senators Jeffords, Frist, Collins, Kennedy, Dodd, Mikulski, Bingaman, Wellstone, Murray, and Reed.

OPENING STATEMENT OF SENATOR JEFFORDS

The CHAIRMAN. The Health, Education, Labor, and Pensions Committee will come to order.

Welcome to the committee's hearing on prescription drug safety and pricing. I would like to extend a special welcome to our colleagues. Senators Johnson, Gorton, Dorgan, Burns, and Congressman Sanders will have the opportunity of testifying first.

Today the committee will consider a very important aspect of health care in America—access to affordable prescription drugs. Specifically, we will consider the issue of price differentials for identical prescription drugs in the international marketplace.

We are all aware of the tremendous scientific advances in medicine that have improved the lives of millions of Americans suffering from many diseases. We look forward to taking advantage of the tremendous new secrets being unlocked through the Human Genome Project. But I think we need to ask what good are all these new wonder drugs if the average American cannot afford to take them?

This is a question that Vermonters and all Americans want answered. Vermonters are well aware that just a few miles away in Canada, for example, the prices of prescription drugs are much lower for exactly the same medicine, made in the same drug manufacturing facility.

The pharmaceutical industry maintains that the current pricing structure is fundamental to maintaining the research and development of new medicines. The questions I have repeatedly asked are: If that is true, why must Americans bear all of the burden of the research and development, if it benefits the whole world? How can we remedy this inequity? And what can Congress do to make medicines affordable to the average American?

Several weeks ago, along with several of my colleagues, I introduced the Medicine Equity and Drug Safety Act of 2000, the MEDS Act, which would give pharmacists and wholesalers the ability to

ensure affordability by using free trade principles to purchase FDA-approved and American-made prescription drugs at lower prices, without compromising the gold standard for safety for which the U.S. Food and Drug Administration is famous.

As I have stated before, the MEDS Act is not the only solution, and it may not be the best solution to the problem of access to affordable prescription drugs. I strongly believe that we need to enact a broad prescription drugs benefit, and I believe we need to find ways to encourage more insurance coverage for more Americans that covers the cost of drugs.

But this is a positive bipartisan measure which we can implement now that will bring prescription drugs prices down for all Americans, and I appreciate the support that Senators Wellstone and Collins on the HELP Committee and Senators Snowe and Dorgan have given us as well.

We all recognize that this is a very complicated issue, and we hope that today's hearing will shed some light on possible solutions. Today we will hear a number of different perspectives on the issue of drug safety and pricing.

Thank you to all of our distinguished witnesses. We look forward to your testimony.

By way of housekeeping, I would ask all of our colleagues who are here this morning and all of our witnesses to be aware that we have a full hearing today, and I will be using the clock more than I normally do to try to keep us on time.

Senator Kennedy will be here shortly, and I will defer to him as appropriate when he arrives.

The CHAIRMAN. Now I will turn to my good friend, the Honorable Slade Gorton.

Senator Gorton, please proceed.

STATEMENTS OF HON. SLADE GORTON, A U.S. SENATOR FROM THE STATE OF WASHINGTON; HON. TIM JOHNSON, A U.S. SENATOR FROM THE STATE OF SOUTH DAKOTA; HON. BERNARD SANDERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VERMONT; HON. BYRON L. DORGAN, A U.S. SENATOR FROM THE STATE OF NORTH DAKOTA; AND HON. CONRAD BURNS, A U.S. SENATOR FROM THE STATE OF MONTANA

Senator GORTON. Thank you, Mr. Chairman. Among others, you are not only a friend, but my next door neighbor in the Hart Building.

I appreciate your willingness to hold this hearing today on a subject that I consider to be vital. You and I are troubled by the same paradox. The United States invents some of the most innovative and effective medicines that treat heart disease, ulcers, depression, and a host of other debilitating and life-threatening diseases. But these same medicines are priced much higher in the United States than virtually anywhere else in the world. Many of our citizens cannot afford the products that were discovered, developed, and manufactured in the United States.

All of us have read accounts of Americans crossing our borders in order to buy vital prescription drugs at deeply discounted prices. Every day, seniors and other Americans can save 50, 60, or even

70 percent on their drug bills simply by going to Canada or Mexico. A bus load of seniors from Seattle recently saved \$12,000 just by driving 2 hours north to buy their medicines at a Canadian pharmacy. These savings are by no means unusual.

Here are just a few examples. The Pecks, from Tacoma, WA, saved \$600 by going to Canada to buy a 3-month supply of blood pressure, stomach, and sinus medications. Tamoxifen to treat cancer costs \$15 for a one-month supply in Canada and \$95 a month in Vermont. Prozac, to treat depression, is just 95 cents a pill in Mexico and \$2.21 per pill in the United States.

My own office conducted, a study, and I was astounded to learn that for the top 10 most commonly prescribed drugs, average prices are 62 percent lower in Canada than in Washington State.

Why are drugs so much less expensive in Canada, Mexico, and other countries? A major reason for this disparity is that foreign governments have implemented price control policies that tempt—successfully, I may say—U.S. drug companies to discriminate against American consumers. Other countries offer to pay nominal costs of manufacturing a drug, some profit and little else. Our drug companies agree, because they can still make a profit, leaving our citizens to pay the high costs associated with research and development of new drugs.

According to the industry, the price other countries pay in no way compensates for the expensive research and development costs for those new drugs. American consumers end up subsidizing the research and development for the rest of the world.

I believe it is time to change the law so that Americans are no longer discriminated against with respect to the cost of prescription drugs. My idea is to borrow from a law that is applied to interstate commerce within the United States for the last 60 years—the Robinson-Patman Anti-Discrimination Act. That Act simply tells manufacturers that they cannot act to undermine one business by selling the same product to a competitor at discounted rates, unless the price difference is due to legitimate quantity discounts.

My bill, "The Prescription Drug Fairness Act," takes these principles and applies them to prescription drug sales overseas. Drug manufacturers would not be able to offer lower price at the wholesale level in Canada, Mexico, or any other country than they charge inside the United States.

Since 1936, the Robinson-Patman Act has established as a legal norm the concept of fair dealing in pricing by prohibiting unjustified price discrimination. The same principle of fair dealing should be applied to prescription drug sales to wholesale buyers in different countries.

What will this proposal mean? Once drug companies have the incentive to charge nondiscriminatory prices overseas, and other countries pay a fair share of drug research and development costs, people in Washington State and across the country will pay lower prices for prescription drugs.

The drug companies have demonized by idea by labeling it "price control." If this is price control, then we have had price controls on every product sold in the United States for the past 60 years. My bill in no way tells drug companies what they can or cannot charge

for prescription drugs. It simply says that they cannot discriminate against Americans.

The kneejerk response from industry to this idea and, quite frankly, to most ideas that lower prices for consumers is that it will hurt research and development. I believe drug companies should be able to recoup the research and development costs for both successful and unsuccessful drugs—but my constituents in Washington and other Americans should not be forced to pay all of those costs for the rest of the world.

When Americans pay higher prices at the drugstore cash register, that is not the first time they subsidize the research and development of new drugs. Taxpayer dollars are used to fund the research conducted by the National Institutes of Health; much of the basic science conducted with NIH grants is then transferred to the private sector. Taxpayer money is also the major source of funds for training scientific personnel, scientists hired by the drug industry in large numbers.

According to a 1993 report by the Office of Technology, in addition to general research and training support, there are 13 programs specifically targeted to fund pharmaceutical research and development. That report noted: "Of all U.S. industries, innovation within the pharmaceutical industry is the most dependent on academic research and the Federal funds that support it."

And finally, there are the tax breaks—for research and development, for orphan drug development, and possession tax credits for manufacturing drugs in Puerto Rico.

Let me be clear. I support America's significant investment in research and development. I have supported all of the programs I just spoke about, including the National Institutes of Health and the research and development tax credit. I also agree that drug companies should be able to recoup costs associated with research and development. But, Mr. Chairman, I do not think that American consumers should be discriminated against by being the only ones to foot the bill. American consumers, who already strongly support R and D efforts through their tax dollars, should not have to pay for R and D tax costs again in the form of higher price at the drugstore. Under my proposal, all users, domestic and foreign, would pay a fair share of those costs.

Unfortunately, I am becoming more and more convinced that drug companies are satisfied with the status quo. They know that they can simply raise prices in the U.S. if other countries negotiate or regulate to win lower prices. American consumers should not be subject to this kind of price discrimination, especially for products that are vitally important to preserving their health.

Congress will continue the debate about adding a prescription drug benefit to the Medicare program. I believe it should do so. The Medicare program must be modernized to reflect the State of health care today.

Adding a drug benefit to Medicare, which the industry naturally supports because it expands its markets, does nothing, however, to address the cost of prescription drugs for the 44 million uninsured Americans and does nothing to address the growing concerns of employers, health plans, and hospitals about rising costs associated with prescription drugs.

As more and more people use prescription drugs, as new drugs are developed, and as coverage for prescription drugs increases, drug costs take more of overall health care spending. But drugs are also costing individual Americans more.

Recently, Families USA released a study that showed the average cost of the 50 drugs most commonly used by seniors rose by 3.9 percent, outpacing the inflation rate. A study from the University of Maryland's Center on Drugs and Public Policy projects prescription drug expenditures will expand 15 to 18 percent a year.

I am convinced that we need to address the issue of price discrimination this year, not only for Medicare patients, but for the health care system overall. My idea is just one way to end the huge differences in prices paid by Americans and people living in other countries for the same prescription drugs and to secure lower prices for American consumers.

There are other ways to achieve the same goal. For example, the bill you have introduced, Mr. Chairman, and a similar bill introduced by Senator Dorgan, would allow pharmacists and wholesalers to re-import medicines that are approved by the FDA and manufactured in FDA-approved facilities. Mr. Chairman, I would be honored if you would add my name to yours as a sponsor of your bill as well.

The CHAIRMAN. Thank you. We shall.

Senator GORTON. It is simply ridiculous that once those drugs leave our border, they are instantly much, much cheaper. Your bill would allow pharmacists and wholesalers to pass discounted prices on to their consumers. While some have raised safety concerns about the practice of reimportation, the Jeffords bill entrusts the Secretary of HHS with maintaining the gold standard of safety established by the FDA. Both re-import bills should help to lower prices for American consumers and may pressure drug companies into offering American consumers lower prices on their own without having to resort to reimportation.

These are two good ideas that get at the price discrimination problem. I am not wed to any one proposal, but what I am committed to is ending this discriminatory practice against American consumers. I will gladly support any idea that any one of my colleagues, the industry, or anyone else comes up with that genuinely addresses the problem.

In the meantime, while seniors and health plans, employers, hospitals and others struggle with the growing cost of prescription drugs, the pharmaceutical industry has been among the most profitable U.S. industries in the last 5 years. So far, they have refused to engage in this debate on pricing.

I hope they will change their minds. Right now, the current system leaves the drug companies' best customers feeling like they have been ripped off. Bob Elmer, from University Place, WA, recently wrote me, and I quote: "I am a recently retired pharmacist and have always been proud of the American pharmaceutical manufacturers and the role that they play in the search for new and innovative entities that help us live not only longer but better. As a matter of fact, I worked for a major manufacturer for some time. I, like you, am outraged at the manufacturers' practice of charging the American public more than the Mexican public or the Canadian

public. What is their rationale for the price differences. This overcharging is a black mark on this industry."

I could not agree more. Drug companies should no longer be allowed to discriminate against Americans by charging higher prices here at home than they do elsewhere in the world. My bill will end that discrimination; so will yours. Americans should be able to buy the prescription drugs they need to stay healthy at an affordable price.

Mr. Chairman, I am in a markup in the Transportation Appropriations Subcommittee, so if you will excuse me, I must leave.

The CHAIRMAN. Thank you for an excellent statement, and your name has already been added.

Senator GORTON. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Johnson?

Senator JOHNSON. Thank you, Mr. Chairman and members of the committee, for holding what I think is a very important and timely hearing. I appreciate being allowed to submit my statement in relation to today's hearing on prescription drug safety and pricing.

The discussion of prescription drug accessibility, affordability and safety has been elevated to new heights in the past year as we in Congress work to develop an efficacious and cost-effective approach to providing some sort of relief for consumers throughout the United States.

Mr. Chairman, I have a chart on my left which indicates the findings of a House committee relative to international drug pricing. For many years, I have heard anecdotal evidence of lower prescription drug prices, certainly in Canada and Mexico. I thought it would be interesting to see a more comprehensive, thoroughgoing study of in fact where are we relative to the prices in other countries, and the finding, I think, is stunning, that in fact it is not just Canada and Mexico, it is virtually the entire Western democratic world paying drug prices roughly half or less than what we pay in the United States. Nobody in the industrialized democracies pays anything close to the price that American consumers are asked to pay for prescription drugs. This is simply an outrage, and this chart indicates the prices, ranging from 51 cents in Italy to 71 cents in Germany per dollar that we pay in the United States.

On June 9 of last year, I joined my colleague from North Dakota, Senator Dorgan, by cosponsoring the International Prescription Drug Parity Act of 1999, and I applaud Senator Dorgan for all of his work on this issue. Additional sponsors of the bill include three of our colleagues—Senators Wellstone, Levin, and Snowe; and Congressman Marion Berry, along with Congressman Sanders, who will be testifying today as well, introduced a companion bill in the House, H.R. 1885, which currently has 84 cosponsors.

The International Prescription Drug Parity Act would allow American wholesalers, distributors and pharmacists to reimport prescription drugs made in the United States that were shipped to foreign distributors. It also provides for a labeling and record-keeping system to ensure that all reimported drugs meet U.S. safety standards. It has been cited by many pro-consumer groups as a positive step toward leveling the playing field for prescription drug prices and would save U.S. consumers billions of dollars by allow-

ing the safe reimportation of American-made, FDA-approved prescription drugs.

One of the red herrings that we hear most often from the pharmaceutical industry is that somehow, if American consumers were allowed to pay a price similar to what other people in the rest of the entire world pay, it would have damaging consequences for the research that goes on in the United States. Certainly, we do not want to interfere with high-quality research in the United States, nor do we suggest that any industry not have an opportunity to make a reasonable profit. But the fact is the pharmaceutical industry currently is making record profits, some three times higher than any other sector of the economy, and it is paying taxes lower than any other sector of the U.S. economy. In fact, there is room to cut American consumers in on the bargain that the rest of the world is benefiting from, or at least to have the same level of benefit as consumers in the rest of the world. Again, this legislation does not set prices. We don't create a bureaucracy to determine what a fair profit and a fair price ought to be. But we do suggest that whatever bargains and whatever leverage other countries manage to negotiate for their citizens ought to be fair game for American consumers as well, whatever price that may be.

The legislation that I am cosponsoring with Senator Dorgan addresses the safety issues of the consumer, which is a second matter which has been brought up. As with any product that passes through multiple distribution channels, it is important that a baseline be established to ensure proper handling and storage; it is particularly critical in maintaining the therapeutic equivalence of prescription drugs. We believe that this legislation will in fact ensure that those safety standards are maintained.

Mr. Chairman, I have heard testimony of every imaginable kind across my State of South Dakota that I thought was particularly compelling. I met with senior citizens in Herreid, SD, and I was told by seniors there that many of them were "snowbirding" to Texas for the winter, and they were paying for the entire cost of their winter stay by the savings that they were gaining from buying their prescription drugs across the border in Mexico.

Now, frankly, a great many of our seniors cannot afford to be traveling to Mexico or to Canada, and they wind up literally choosing between groceries and staying on their prescription drugs, ultimately winding in the emergency room with an acute illness, at which time the taxpayers then pick up the tab through Medicare.

I think the urgency of this issue, Mr. Chairman, is enormous. All of us are hopeful that we will find a bipartisan consensus that will allow for prescription drug coverage of some sort through Medicare that would not only provide for increased coverage but would also address the cost containment issues.

But I do not think that we can wait to reach that point of grant bipartisan consensus which may or may not come this year. There are steps that we can take now that would have immediate and enormous consequences for consumers all across this country. Seniors comprise about 12 percent of our Nation's population but consume about 35 percent of the prescription drugs. Over one-third of them have no Medigap policy whatsoever, and they are literally choosing between groceries and rent and the cost of prescription

drugs, while looking at their neighbors not only in Mexico and Canada, but virtually every other Western democracy on the planet, and noticing that they are paying half the price or less than what we pay.

This is an intolerable situation, Mr. Chairman, and I am pleased to join Senator Dorgan, and I am pleased that Senator Gorton and others have looked at alternative approaches as well as your approach. I believe that we need to pass this legislation this year. If we reach a final, more comprehensive conclusion at some other time, I applaud that, but there is no excuse for not moving forward aggressively with this legislation now.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, and thank you as well for your very useful chart and for all the work that you put into your presentation.

[The prepared statement of Senator Johnson may be found in additional material.]

The CHAIRMAN. Congressman Sanders, we are pleased to have you here. Vermont has been made much more aware of the problem than probably anywhere else, and we praise you for your work in that area.

Please proceed.

Mr. SANDERS. Thank you very much, Senator Jeffords, and thank you very much for holding this important hearing.

As you know, Senator, just about this time last year, I took a group of citizens from our State across the Canadian border, and what we learned on that trip is what others have already told you and you know—that the cost of prescription drugs in Canada is substantially lower than it is in the United States. That is also the case in Mexico, and as Senator Johnson just indicated, that is true of every country in the entire world.

Let me be personal for a moment. I think every person in this room knows that we are suffering from an epidemic of breast cancer in this country, and God knows how many women are struggling for their lives against that killer disease. One thing that appalled me on the trip that I took to Canada—and we took a number of women from Vermont with us on that trip—was that they were able to purchase the widely-prescribed breast cancer drug, Tamoxifen, in Canada for one-tenth of the price that they were paying in Vermont or anyplace else in the United States.

So here you have a situation where women are fighting for their lives and are paying ten times more for Tamoxifen, widely prescribed for breast cancer, than in the case in Canada.

And let us be very sure to note that the manufacturer of that drug makes a profit in Canada or wherever else that drug is sold.

You have heard from Senator Johnson what is absolutely true, and let us reiterate one point here. When we talk about drugs being more expensive in the United States, we are talking about exactly the same product, most often manufactured here in the United States. So that in fact what we are talking about is a monumental rip-off of the American people by an industry which year after year enjoys recordbreaking profits and the highest profit of any industry in this country. So that while they make \$20 billion

a year in profits, they charge the elderly and the sick in this country grossly inflated prices compared to any other country on earth.

Now, Mr. Chairman, let me raise a sensitive issue, something that my other colleagues have not yet mentioned, but I think it is important to raise. And that is that what we are talking about today is not only the outrageously high cost of prescription drugs, as important as that is, but we are talking about the credibility of the United States Congress, the Senate, and the House to represent the people of this country.

As you know, Senator, the majority of the people in this country have given up on the political process. They no longer vote. They no longer believe that the Congress represents their interests. They believe, and I might add, quite appropriately, that the United States Congress is by and large in the pocket of the big money interests. And the reality is that the pharmaceutical industry not only enjoys recordbreaking profits, more than any other industry, not only gets huge tax breaks, not only gets huge subsidies from the taxpayers, but there is something else that they do. That is, they spend more money on campaign contributions and on lobbying than any other industry—and let us be frank—the majority of the Members in the Senate and the vast majority of the Members in the House receive campaign contributions.

The issue today is whether the Congress has the guts to represent the American people against the big money interests who are flooding Capital Hill with campaign contributions, who are spending millions and millions of dollars on dishonest television ads, who run a phony organization called "Campaign for Better Medicare," sending out millions of letters all over this country.

What the issues comes down to is do we have the guts to represent the elderly and the sick, or is the pharmaceutical industry, with all of their money, going to continue to rip off the American people. And that is the issue.

Now, how do we solve the problem? I want to congratulate you, Senator Jeffords, and others in the Senate, and I want to congratulate 85 colleagues in the House for coming up with what I think is a very simple, straightforward piece of legislation that would substantially reduce the cost of prescription drugs in this country. The International Drug Parity Act is what we call it in the House, and similarly in the Senate, your bill is very similar.

What does it say? What is so radical about this idea? We live in an increasingly global economy—and I must tell you that I have various problems with aspects of that global economy—but what this means is that if you are a businessman in the United States, and you are in the shoe business, and you want to purchase your shoes in Mexico and sell them in the United States, you go down to Mexico and you purchase your shoes; and if you are in the vegetable business, you want to buy lettuce in Mexico that we can eat this afternoon in our cafeteria, and you go down to Mexico or anyplace else in the world where you can purchase inexpensive lettuce, and you sell it right here in the United States.

So I want to know if the global economy is good for all of those areas, why is the global economy and free enterprise and competition that we hear so much about not good for prescription drug distributors in this country? Why is it not good for pharmacists in

Northern Vermont? Why can't they purchase exactly the same drug, manufactured by exactly the same company, for 50 percent or 70 percent lower cost in other countries of the world and sell that product in the United States? This is a very simple proposition. I hear a lot about competition and free enterprise. Let us have some competition and free enterprise regarding prescription drugs in this country.

The one red herring that is brought forth by the pharmaceutical is the safety issue. I have confidence that the FDA will be fully able to address this issue. If we can import lettuce into this country, produced on hundreds if not thousands of farms, certainly we can make sure that the quality of reimportation into this country is of the standard that we want it to be.

So, Mr. Chairman, let me also say that I happen to believe that there must be a very strong prescription drug benefit under Medicare. How do the two issues relate? The fact of the matter is that neither the Republican nor the Democrat proposal will be strong enough unless we lower the cost that the government is going to have to pay for prescription drugs.

So I think that what we have got to do is pass your legislation or legislation in the House which will substantially lower the cost of prescription drugs, and that will help us to provide a strong benefit program under Medicare, because what the government will be paying for that drug is much less than is currently the case.

The eyes of the people of the United States are on what we are doing here, and I would hope that the Members of the Senate and the Members of the House will have the guts to tell the pharmaceutical industry what they can do with their money and to stand up for the average American consumer and pass your legislation or my legislation this year, as soon as possible. Millions of lives and the alleviation of a lot of suffering depend on whether we can do that.

Thank you.

The CHAIRMAN. Thank you very much, Congressman, for that very forceful statement.

Senator Dorgan?

Senator DORGAN. Mr. Chairman, there is not a lot left to say, actually, but let me say it anyway.

The price of prescription drugs is a significant and a real issue in this country. I commend the pharmaceutical drug industry for the work they do in research. I commend them for some of the life-saving prescription drugs they have developed. But I certainly do not commend them for their pricing policies.

It is especially a serious problem for Medicare beneficiaries, who have reached the lower-income stage of their lives, to discover that those prescription drugs which can save their lives and give them better lives are often out of the reach of senior citizens who are now living on fixed incomes, because the prescription drugs are priced out of reach.

So we have, as Senator Johnson indicated, 12 percent of the population consuming one-third of all the prescription drugs. Last year, the cost of prescription drugs increased 16 percent in 1 year alone; a substantial part of that is utilization, a substantial part is price inflation, another part is new drugs.

I have held hearings on these issues in seven or eight States now as chairman of the Democratic Policy Committee, and it does not change from one State to another. Senior citizens come to me and say: When I go to the grocery store, I have to go to the back of the store first, where they sell the pharmaceutical drugs, so I can buy the pharmaceutical drugs I need, and then I will know how much money I have left for food.

The doctor in Dickinson, ND said that his patient who had breast cancer and had had mastectomies was told by the doctor that she had to take a certain medicine in order to lower the chances of recurrence of the breast cancer, and the woman said to the doctor: There is no way I can do that; I do not have any money. I cannot possibly afford that medicine. I am just going to have to take my chances.

You hear these stories all across this country.

I have some prescription drug bottles that I have brought today—there are no drugs in the bottles. This is Zocor. I want to show the committee what we are talking about. Zocor is used to lower cholesterol, and there were \$1.7 billion in U.S. sales last year. This is Zocor marketed in Canada, and this is Zocor marketed in the United States. They are both 20 milligram pills. The price in the United States for one pill from this bottle is \$3.82 wholesale—that is \$3.82 wholesale for one pill. The same company, the same pill, the same bottle in Canada—\$1.82 for one pill. The same pill is paid double in the United States.

Zoloft by Pfizer, which is used to treat depression, had \$1.4 billion in U.S. sales. If you buy it in Canada, it costs \$1.28 for a 50 milligram tablet; if you buy it in the United States, it costs \$2.34. It is the same pill, the same bottle, the same company, but the U.S. consumer pays \$2.34, and the Canadian consumer pays about half of that, \$1.28.

Norvasc is used to reduce blood pressure and is produced by the same company. The U.S. wholesale price is \$1.25. The Canadian price is 90 cents.

I want to challenge just one Member of the House or the Senate—I want to find just one Member of the U.S. House or the U.S. Senate who will stand up and say publicly that they think this is fair pricing. Just one—I am not asking for a dozen Members of Congress to stand up and do this—I am just asking for one brave but misguided soul to stand up in either the House or the Senate and say: For Zoloft, we believe the American consumer should pay double the price of the Canadian consumer for the same product put in the same bottle.

I am asking for one person to stand up and do that, and I will bet you there is not one Member of the House or the Senate who will stand up and say this is fair pricing—not one.

And the question that Congressman Sanders asks is a fair one—if every Member of Congress believes this is unfair pricing, then will the Congress do something about it, and if not, why not?

I have given you the wholesale prices for these drugs, so you can see that the differences are attributable to pricing practices of the manufacturers, not the retailers.

These are not isolated findings. You have all seen the 1992 GAO study that shows that a market basket of 121 identical prescription

drugs available from the same manufacturers would cost wholesalers 32 percent more in the United States than in Canada. A prescription drug costing \$1 in the United States costs 51 cents in Italy, 57 cents in France, 64 cents in Canada—and the list goes on; I am not going to go over it all again.

The U.S. drug industry is enjoying all the advantages of global trade. They can access from anywhere in the world the ingredients for production, the labor for production, the raw materials and so on, and then they can import those drugs into the United States and Canada. The question then is should the United States consumer have access to the same fruits and benefits of free trade.

Americans are not free, unfortunately, to access the benefits of free trade.

I introduced a bill, and I want to say it is not the “Dorgan bill”—I introduced it with my colleagues, Senators Wellstone, Snowe, and a number of other folks; we wrote it jointly—we introduced a piece of legislation saying that if free trade is good for everybody, let us make it good for the American consumer as well. And while we have done that, there are now \$20 to \$30 million worth of fraudulent ads running on television in my State, and I suspect in your State, Senator Jeffords, and here in Washington, DC by a group called Citizens for Better Medicare. It is actually the pharmaceutical manufactures in a “Big Bird” uniform. But the fact is it is fraudulent advertising, and it is going on week after week after week, spending millions of dollars on fraudulent and dishonest ads on this issue.

I know your time is short, Mr. Chairman, so let me just say two additional things. The only objection to preventing the American people from accessing these same drugs at competitive prices or at less expensive costs in Canada or elsewhere is the drug industry’s claims that, well, gee, this would jeopardize chain of custody.

That is nonsense, total baloney. Do you think that the drug that is put in the drugstore or the pharmacy in Winnipeg, Canada does not have a chain of custody that protects that consumer? Of course, it does. It is just that we will not allow the pharmacist from Grand Forks to go up and access that same drug. It is interesting—they kill a hog in Canada and put the pork from that hog on a truck, and they pull a strip of meat off the back and lay it in the back of that drug, so when they open the door, they can find that one strip of meat. Who does that? The Canadian packer; that is who does it. And we accept that. We say that is fine; that is okay—you can ship all that pork in here from dead hogs, and we will just accept a little strip. We may not even open the truck, but if you do, whatever you pulled off, we will say that is good enough for us. But now we are worried about the safety of the chain of custody on drugs in Canada? That is total baloney. It is a specious argument, and everybody knows it.

Well, it has been therapeutic to be able to come and say all this again this morning. We must do something about this issue. This is life or death to folks out there. There are people living on fixed incomes who cannot afford these prices. I went to Emerson, Canada and stood in the drugstore up there with a group of North Dakota senior citizens and discovered what I knew before I went—that is, the same drug, put in the same bottle, made by the same manufac-

turer is sold for a fraction of the cost; half the price in Canada, one-third the price in Mexico. And the question that I will leave you with is this: Why should an American citizen have to go to Canada to purchase a drug that is produced in the United States to save half the cost? Why on earth should that be the case?

My goal is not to have Americans rushing abroad to buy drugs. My goal is to force the repricing of drugs in this country, and that is what will happen with a true global economy in which consumers have the same power as pharmaceutical manufacturers.

Mr. Chairman, thank you for allowing me this opportunity to testify.

The CHAIRMAN. Thank you for an excellent statement.

Senator Burns, please proceed.

Senator BURNS. Thank you very much, Mr. Chairman.

Everything has been said, but everybody has not said it—I think that is how the saying goes. My statement will be very short, and I ask that my complete statement be made a part of the record, however, as we work our way through this thing.

The CHAIRMAN. It will be.

Senator BURNS. Mr. Chairman, thank you for your leadership and the leadership of this committee in dealing with a problem and situation that is very difficult. Everybody in this room understands the gravity of the situation. Reducing cost has become a national issues, with numerous proposals now pending before Congress.

Mr. Chairman, I have taken a position that is pretty simple. The road to the solution will be fraud with twists and turns that could in effect have great consequences on generations to come behind us. As you know, what we do today does not affect many people in the near future, but when you take a look at the next generation, it surely affects them. The same could be said about the well-being of those who depend on life-saving drugs now and those miracle drugs that are in the process of being developed now.

So I have developed a guide for me as we assess the problem and search for the solution—security, safety, and doing the responsible thing should be our guideposts in the days ahead during the discussions and this debate.

Let us take a look at history a little bit. I think that is in order. When Congress passed the Prescription Drug Marketing Act of 1988—nobody wants to talk about that much—they did so out of concerns for drug safety and counterfeit drugs. I was not here then. The legislation was well-defined and well-intentioned. Even today, the Food and Drug Administration estimates that about one-fourth of the drugs coming out of Mexico are counterfeit.

Safety is key as we look for ways to lower the cost of prescription medicines, whether purchased through internet sales or foreign sources. That is not to say that something cannot be worked out with regard to the movement and the cost of drugs over international borders.

In 1965, 35 years ago, few prescription drugs had clinically significant effects in treating the diseases that are common among our elderly population. Research and development plus good science has resulted in an enormous increase in the number of effective drugs available today that prevent as well as treat. It is a factor that must be considered in these discussions.

On Medicare, the program itself must be modernized and reformed. Everybody in this room understands and knows that. In doing so, adding expensive programs will only make that modernization more difficult. HCFA, in its financing of the program, must work with Congress in reforming its own rules and regulations so that prescription drug benefits can be offered and financed in a way not to place the entire Medicare system in financial jeopardy. HCFA is micromanaging the program now. With over 100,000 pages of rules and regulations, it is impossible to adapt to the rapid changes and advances in medicines and the whole health care delivery system.

That has a lot to do with the entire system and will also be a part of the drug benefit unless we do it right. We have the responsibility to the next generation as the financial burden will fall on them.

I believe we need to look at the issue of prescription drugs in the overall context of improving our health care delivery and financing system. Price and safety are two key elements, but not all. We should consider tax credits that could be put forward in the purchase of health insurance for those who fall through the cracks, folks who earn too much income for public assistance yet are without employer-sponsored plans or other plans.

However, I do not think that we can just isolate the issue to the price of medicine and say we are done with it. Strengthening the solvency of Medicare is imperative. We owe it to our seniors. But there is another element of American society—what about individuals with disabilities, and others who rely on medication to take the responsible and comprehensive approach in addressing the price and the availability of prescription drugs?

I think we all agree that we must also bear in mind that folks who give some of their hard-earned dollars to finance a system deserve some of our attention also. If we do it right, the problem becomes even more complex in the new future with a new generation of drugs that offer a quality of life never surpassed in the history of man on this planet. The promise of longer and healthier lives is wonderful, but it comes with a price, and my fear is that most Americans will not be able to afford them.

It falls on us to assure that every American gets what the doctor ordered.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burns, for an excellent statement, and I want to thank all of you for your statements. And I have made mine, so I will turn to Senator Frist for questions or however he would like to use his time.

Senator FRIST. Thank you, Mr. Chairman, and I want to thank all the witnesses and colleagues who have presented today, because I think they have introduced the topic of prescription drugs pricing and safety in a very sophisticated way and showed that the range of issues is broad; it is a serious problem, it is something that we all hear about on a daily basis as we conduct our town meetings around our various districts and States.

The whole issue of affordability and safety of prescription drugs today becomes increasingly important as prescription drugs become

a more and more important part of the armamentarium of our medical profession today.

Twenty years ago, prescription drugs simply were not as important. The number of prescription drugs and individuals on them was probably four- to five-fold smaller than it is today, and as we look to the future over the next 5 or 10 years, increasingly, people will in all likelihood be on more and more prescription drugs. The rate of increase in terms of how much is spent is running 16 to 17 percent a year, and that is going to continue in the future because of increased demand and for the three reasons that Senator Dorgan mentioned.

It is going to take a multifaceted approach, and most of the presentations today have not focused on an issue that I want to at least mention, and I know in the panels to come, we will be focusing on, and that is the safety issue.

Congressman Sanders mentioned—and we will come back to it again and again because it is a fundamental issue—the reimportation of drugs that are manufactured under what we like to think are standards equal to the United States but in other countries that might not have as high quality as we have in the United States.

I mention that, and again, I think we will hear much more about it, but people like the current FDA Commissioner, Dr. Henney, have expressed their concerns; there is a letter which I am sure will be quoted later this morning from Dr. David Kessler in June to Representative John Dingell. Dr. David Kessler, as everyone knows, is the former FDA Commissioner. When it comes to the reimportation of drugs, he says—and let me just read one sentence of that letter—“In my view, the dangers of allowing reimportation of prescription drugs may be even greater today than they were in 1986. For example, with the rise of internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years. Repealing the prohibition on reimportation of drugs would remove one of the principal statutory tools for dealing with this growing issue.”

That is just one paragraph out of a long letter. I know people will be referring to it over the course of the morning.

Other statements that have been made in the past include Dr. Gerry Goyen, former dean of the University of California at San Francisco School of Pharmacy and FDA Commissioner under President Carter, who has written: “There is no provision for assuring that the drugs, once out of the manufacturer’s control, are not replaced by counterfeit products that look like the original.”

I mention these—and we can refer back to the House Commerce Committee hearing last week when the example was given of gentamicin, that in our efforts to slow down this growth in pharmaceutical costs, we address it in a balanced and carefully thought out way, recognizing the limitations of the Food and Drug Administration in terms of their oversight ability.

Let me turn to Congressman Sanders, because you have probably heard and participated in the testimony on the House side. Last week in the House Commerce Committee, on this issue of lack of critical oversight by the FDA in manufacturing drugs, one of the facts was that the FDA had inspected only 24 percent of foreign

manufacturers of counterfeit bulk drugs and that these drugs may have led to the deaths of 17 Americans. That example was with gentamicin sulfate, which is used to treat infections of the blood and bacteremia.

How much of a concern is that to you as we reach out, recognizing the limitations of FDA today?

Mr. SANDERS. It is a very legitimate and real concern, and I thank you for raising the issue. You mentioned that letter from Dr. David Kessler. Do you know when I first saw that letter, coincidentally? It turned up at a television station in Burlington, VT 1 day before I went over to Canada, to talk about the low cost of prescription drugs—and I am sure it was just a coincidence.

But this is, of course, the issue that the pharmaceutical industry is raising, and you are right to raise it. Does anyone here think that Senator Dorgan or myself or anybody wants to see a situation where drugs are brought into this country which are not 100 percent safe? And the answer, obviously, is no. This is a legitimate concern.

And Senator, in order to deal with that concern, my office—and we have been working with Senator Jeffords on it—has been sitting down with the Food and Drug Administration, because we want them to be able to tell us at the end of the day that they have a mechanism which has been developed to make sure that every, single product comes into this country.

Now, Senator Dorgan raised an interesting issue. Pork comes across the border. Lettuce comes across the border. All kinds of products that we eat come across the border, which I presume are produced on thousands of small farms and ranches, correct, and we accept that into this country. Given that reality, do I not believe that the Food and Drug Administration is capable of developing a) a paper trail—where is the product manufactured, where is it stored, when did it come into this country—and b) a testing mechanism at the border to make sure that the product coming into this country is 100 percent safe.

So you raise a legitimate concern, and before I sign off on any legislation—and our bill includes that—I want to make very sure that the product is safe.

Senator FRIST. I think——

Mr. SANDERS. But Senator, let me just——

Senator FRIST. Let me just interrupt, because I have heard your point, but since you have said it twice, lettuce importation into this country is different than gentamicin sulfate to treat a life-threatening bacterial endocarditis where somebody is going to be dead within 24 hours. And you have said it three times. That bothers me even more, because if we use the same standards that we use for importing lettuce into this country to import whether it be gentamicin or whether it be just routine drugs to treat rheumatoid arthritis, if that is our mentality, I think we are in trouble.

Mr. SANDERS. No. My point was that if you and other Members have accepted that safety criteria for a product produced on hundreds and thousands of farms, surely, where you have a product that is manufactured by a relatively few companies, we can administer it. And I would hope that you would agree with me that when you talk about safety and the potential danger that you will ac-

knowledge today, because millions of people are not getting the prescription drugs that they need, and they are dying and they are suffering today, and that we face a crisis and that we must lower the cost of prescription drugs.

Senator FRIST. Thank you, Mr. Chairman.

Just one other comment very quickly. I think that your comment about prescription drugs and the price of prescription drugs tying in what we do with the uninsured with Medicare is real, because prescription drugs apply to everybody across the board, and what we do here will, I think, help other programs broadly.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Frist.

Senator Wellstone?

Senator WELLSTONE. Thank you, Mr. Chairman.

I am not going to make an opening statement—let me just include that in the record—we have a lot of good witnesses today, and I look forward to introducing Steve Schondelmeyer from Minnesota, who has done some fabulous work that I think will also speak to some of the questions that Senator Frist has raised.

So let me just ask unanimous consent that my full statement be included in the record.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Wellstone follows:]

PREPARED STATEMENT OF SENATOR WELLSTONE

Mr. Chairman: I want to thank you and salute you for calling this important hearing. I am glad we have begun the process of taking testimony so we can proceed to marking up legislation that corrects the injustice that finds American consumers the least likely of any in the industrialized world to be able to afford drugs manufactured by the American pharmaceutical industry because of the unconscionable prices the industry charges only here in the United States.

Mr. Chairman, when I return to Minnesota which I do frequently, I meet with many constituents, but none with more compelling stories than senior citizens struggling to make ends meet because of the high cost of prescription drugs—life-saving drugs that are not covered under the Medicare program. Ten or twenty years ago these same senior citizens were going to work everyday—in the stores, and factories, and mines in Minnesota—earning an honest paycheck, and paying their taxes without protest. Now they wonder, how can this government—their government—stand by, when the medicines they need are out of reach.

But it is not just that Medicare does not cover these drugs. The unfairness which Minnesotans feel is exacerbated of course by the high cost of prescription drugs here in the United States—the same drugs that can be purchased for frequently half the price in Canada or Mexico or Europe. These are the exact same drugs, manufactured in the exact same facilities with the exact same safety precautions. A year ago, most Americans did not know that the exact same drugs are for sale at half the price in Canada. Today, you can bet the pharmaceutical industry wishes no one knew it. But the cat is out of the bag—and it is time for Congress to right these inequities.

All the legislators sitting in front of me, the Chairman and I have heard the firsthand stories from our constituents—in Minnesota, Vermont, North Dakota, South Dakota, Washington state—constituents who are justifiably frustrated and discouraged when they can't afford to buy prescription drugs that are made in the United States—unless they go across the border to Canada where those same drugs, manufactured in the same facilities are available for about half the price. Senior citizens have lost their patience in waiting for answers—and so have I.

Driving to Canada every few months to buy prescription drugs at affordable prices isn't the solution; it is a symptom of how broken parts of our health care system are. Americans regardless of party have a fundamental belief in fairness—and know a rip-off then they see one. It is time to end that rip-off.

While we can be proud of both American scientific research that produces new miracle cures and the high standards of safety and efficacy that we expect to be followed at the FDA, it is shameful that America's most vulnerable citizens—the chronically ill and the elderly—are being asked to pay the highest prices in the world here in the U.S. for the exact same medications manufactured here but sold more cheaply overseas.

That is why I introduced with Senator Dorgan the International Prescription Drug Parity Act, and with Senator Jeffords the Medicine Equity and Drug Safety Act, two bills which will amend the Food, Drug, and Cosmetic Act to allow American pharmacists and distributors to import prescription drugs into the United States as long as the drugs meet FDA's strict safety standards. Pharmacists and distributors will be able to purchase these drugs—often manufactured right here in the US—at lower prices overseas and then pass the huge savings along to American consumers.

What these bills do is to address the absurd situation by which American consumers are paying substantially higher prices for their prescription drugs than are the citizens of Canada, and the rest of the industrialized world. These bills do NOT create any new federal programs. Instead they use principles frequently cited in both house of the Congress—principles of free trade and competition—to help make it possible for American consumers to purchase the prescription drugs they need.

And the need is clear. A recent informal survey by the Minnesota Senior Federation on the price of six commonly used prescription medications showed that Minnesota consumers pay, on average, nearly double (196%) that paid by their Canadian counterparts. These excessive prices apply to drugs manufactured by U.S. pharmaceutical firms, the same drugs that are sold for just a fraction of the U.S. price in Canada and Europe.

Pharmacists could sell prescription drugs for less here in the United States, if they could buy and import these same drugs from Canada or Europe at lower prices than the pharmaceutical companies charge here at home.

Now, however, Federal law allows only the manufacturer of a drug to import it into the U.S. Thus American pharmacists and wholesalers must pay the exorbitant prices charged by the pharmaceutical industry in the U.S. market and pass along those high

prices to consumers. It is time to stop protecting the pharmaceutical industry's outrageous profits—and they are outrageous.

In the words of the editors of Fortune Magazine, "Whether you gauge profitability by median return on revenues, assets, or equity, pharmaceuticals had a Viagra kind of year."

Let's take a look at the numbers, so there can be no mistake:

Where the average Fortune 500 industry in the United States returned 5% profits as a percentage of revenue, the pharmaceutical industry returned 18.6%.

Where the average Fortune 500 industry returned 3.8% profits as a percentage of their assets, the pharmaceutical industry returned 16.5%.

Where the average Fortune 500 industry returned 15% profits as a percentage of shareholders equity, the pharmaceutical industry returned 36%.

Those record profits are no surprise to America's senior citizens because they know where those profits come from—they come from their own pocketbooks. It is time to end the price gouging.

These hearings, Mr. Chairman, will help us move along legislation that can assure our Senior Citizens and all Americans that safe and affordable prescription medications at last will be as available in the United States of America as they are in all the other countries of the industrialized world.

Senator WELLSTONE. And let me just emphasize two quick points and then go to the legislation. First, we all speak about our own States, and in my State of Minnesota, for a set of complicated reasons having to do with inadequate Medicare reimbursement vis-a-vis managed care and prescription drug coverage, we have at best 35 percent of senior citizens with any coverage at all. Literally two-thirds of the senior citizens in the State of Minnesota have no prescription drug coverage at all. This is a huge issue, and Congressman Sanders, along with what you said about those who cannot afford it, the danger of that is also all the people that you meet—all of us have met people—who are literally cutting these pills in half and in thirds. They do it, and then you talk to their doctors and others, and they say this is actually more dangerous than if they did not take them at all. So I think this is really an issue of crisis proportion.

The second point, to go to an important question that Senator Frist raised, is that I think—since I am working on this legislation with Senator Dorgan and Congressman Sanders and also working on the other bill with Senator Jeffords and Senator Collins—that frankly, our legislation merges in a way, given what Congressman Sanders just said by way of response. That is, with the bill that we are working on with Senator Jeffords, basically, what we are saying is that this takes effect as long as the drugs meet FDA safety standards. That is what you want to sign off on. Frankly, I think we can easily reach some agreement on that. That is the direction I think we are going in.

I want to make one final point and then raise some questions. This is a "Dorganism," or at least, this sounds like the kind of statement that Congressman Dorgan would make, but it is not from Congressman Dorgan; it is a quote from the editors of Fortune Magazine. I quote: "Whether you gauge profitability by median re-

turn on revenues, assets, or equity, pharmaceuticals had a Viagra kind of year." Let me repeat that, because when we hear all of these arguments that it cuts into our budget for research, and we think about the challenge that Congressman Sanders has raised for us today, which is, Congress, whom to you belong to, whom do you represent—do you represent the people back home, or do you represent this powerful industry? In the words of the editors of Fortune Magazine, "Whether you gauge profitability by median return on revenues, assets, or equity, pharmaceuticals had a Viagra kind of year."

It is really quite incredible to look at the excessive—I mean, they are for profit—but I would argue the proposition that so much profit and price-gouging can be made off the misery, illness and sickness of people, especially senior citizens, is obscene. So I think we are faced with these questions.

Let me put a question to both of you. I want to ask you to draw the linkage between—because I agree with Senator Frist on this point—I think there really is a very important linkage between expanding Medicare coverage and having some way of cost containment. Otherwise, you expand Medicare coverage, covering prescription drug costs, and it is a blank check. Somehow, there has to be some accountability here; otherwise, we will not be able to afford it. Government cannot afford it, people will not be able to afford it, and it will be one of those programs that people will then say was counterproductive and did not work.

My question, above and beyond the statement I just made, is what, beyond price reduction, do you see as being the benefit of the legislation that each of you have presented? In other words, a lot of people say, well, you are talking about price reduction, but you still have a lot of people who are not insured. How do you see these two efforts as being interrelated, the effort of making sure people are insured and the way in which you are focusing on price reduction?

Senator DORGAN. Senator, I am not sure I understand the full import of your question, but if we pass this legislation, it will force a repricing of prescription drugs in this country. That is clear. If consumers can access the same drug for a fraction of the cost elsewhere—and I would say to Senator Frist that we are only talking in the legislation that we propose—and I do not know of anyone who is speaking differently—we are only talking about drugs approved by the FDA and where there is proper inspection and where the chain of custody has been assumed to be safe—if we pass legislation like this, it will force a repricing of those prescription drugs in this country. And if we put a prescription drug benefit in the Medicare program, which I believe we should, and do nothing with respect to the price issue, it is tantamount to hooking a hose up to a tank, and it will not be long before the tank is dry. I mean, there has been a 16 percent increase in 1 year in prescription drug costs, and again, a substantial part of that is utilization, some price inflation, and some new drugs.

It seems to me we must address the prescription drug piece of Medicare with thoughtful approaches that will tend to put some downward pressure on prices, and this legislation will do that. People say, well, it is importing the price control regimes of foreign

governments. Nonsense; that is baloney. When you buy a pair of trousers from China, are you importing the cost of Communism for the price of pants that Jiang Zemin wears? This is globalization. If you are going to swallow globalization, you get all the fruits of it, and some taste sweeter than others. But if the same company is selling this drug for a fraction of the price in Canada, then our consumers, if we assure the chain of custody and the safety of supply, ought to be able to go there and access that for half the price. That will force repricing in this country.

Senator WELLSTONE. Congressman Sanders?

Mr. SANDERS. I would just add to what Senator Dorgan said by saying that already, in some of the drugs—and Senator Frist, I point this out in response to your concerns—as you know, some of the content in some of our drugs today manufactured in the United States comes from abroad, as a matter of fact. So I think we want to apply all the principles of globalization, as Senator Dorgan mentioned.

But here is the other point. Both the Democrats and the Republicans are looking at alternative plans to cover senior citizens, and neither one of these plans is terribly strong. And one of the reasons why neither one of these plans is terribly strong is because they both assume that you are going to have to pay a lot of money for the drugs.

If we did nothing more than pass Senator Jeffords' bill or our bill or Senator Dorgan's bill and lower the price of prescription drugs substantially, we can provide a lot more for a lower price to seniors in Medicare.

Senator WELLSTONE. I thank both of you for your response, but I think you just made a critically important point, and Mr. Chairman, I think that is one way that these efforts are in a very crucial way interrelated. I want to thank both of you again. It is a huge issue, not just for elderly people. We have a great organization in Minnesota for the record called the Minnesota Senior Federation, and you met a good number of them when you came to our State, Senator Dorgan, and I will be crossing over into Canada with them this August in their effort to continue to raise Cain about this until we act here in the Congress.

[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend Senator Jeffords for holding this important hearing. The high cost of prescription drugs is imposing a heavy financial burden on our citizens, particularly the elderly, many of whom must pay out-of-pocket for expensive medications. The need for action is clear and urgent. We must pass a Medicare prescription drug benefit before this session of Congress ends.

For many years, Americans have paid more for the same pills than consumers in other countries. U.S. drug prices are typically one-third higher than the cost of the same products in Canada.

The high cost of drugs in the United States has led many of our citizens to ask for access to cheaper medications from abroad. Several well-intentioned legislative proposals before this Congress would permit imports of lower-priced medications from other countries. Clearly, before taking any such action, we need to be able to

guarantee that U.S. consumers are receiving legitimate, FDA-approved products, so that the American public is not at risk of receiving contaminated, counterfeit, or ineffective medications. The high standards we take for granted in this country are not shared by many other nations.

In addition, Americans who lack prescription drug coverage may not see the full cost savings from buying imported medications. Foreign brokers, large purchasers, and others will likely vie for the lion's share of these savings.

Importing lower-priced medications is no substitute for coverage. Providing a Medicare prescription drug benefit can lead to substantially lower costs for U.S. drugs for our senior citizens.

We know that high prices today are creating barriers to effective drug therapy and limiting access to medications for many Americans who lack prescription drug coverage. As a result, they do not receive adequate treatment for their conditions. Thirteen percent of older Americans—more than 1 out of every 8—are forced to choose between buying food and buying medicine. Ten percent of Medicare recipients without drug coverage reported that they did not fill a prescription in the past year because they could not afford it.

Too many seniors are paying twice as much as they should for the drugs they need, because they are forced to pay full price, while almost everyone with a private insurance policy benefits from negotiated discounts. Pharmaceutical products are increasingly the source of miracle cures for a host of dread diseases—but senior citizens are being left out and left behind because Congress fails to act.

Congress must pass a Medicare prescription drug benefit that covers all senior citizens, provides both basic and catastrophic coverage, and is affordable.

Millions of Americans with private insurance coverage pay much less for prescription drugs than seniors pay. Private purchasers who buy in bulk—such as HMO's, insurance companies, and large corporations—all receive substantial discounts. Any Medicare prescription drug program should be set up to provide the benefits of bulk purchasing, and those benefits should be available to all seniors. With private sources of coverage becoming increasingly inadequate, unreliable, and inaccessible to many of the elderly, the need for a Medicare prescription drug benefit with universal coverage has become greater than ever. A third of Medicare beneficiaries lack any drug coverage today.

Medicare should cover both basic prescription drug costs and catastrophic expenses. The basic coverage will meet the needs of senior citizens with moderate drug costs, and catastrophic coverage will protect those who need very expensive medications. Increasingly, the price of many new miracle biotech drugs exceeds levels that seniors without coverage can afford.

Also, many seniors suffer from multiple medical conditions that require treatment with several prescription drugs. As a result, the total package is often priced far beyond their means. Seniors with high medication expenses need catastrophic coverage to ensure that they receive the medications they need.

Any program we enact will still leave seniors responsible for paying a portion of the costs. Elderly Americans do not want welfare.

All senior citizens are entitled to a fair price—the same fair price that is given to other large purchasers of prescription drugs. The elderly are willing to pay their fair share—but today they pay far more, and that is unacceptable.

There is still time for this Congress to pass a Medicare prescription drug benefit that provides our senior citizens with the health security they deserve. It is long past time to close this serious gap in their current coverage.

The CHAIRMAN. Thank you.

I would remind members that we have two panels anxiously waiting to testify. On the other hand, I want everyone to have an opportunity to question this panel.

Senator Collins?

Senator COLLINS. Thank you, Mr. Chairman.

I want to thank you for holding this tremendously important hearing to explore the disparity in prices that American consumers pay versus their counterparts in other countries. This is of great interest to me, coming from a border State where a lot of Mainers find that they can better afford their needed pharmaceuticals by getting a Canadian doctor to write them a prescription and buying them across the border.

That is of great concern to me. This whole issue presents a very interesting paradox. Here, the United States is the source of the cutting-edge research and development and manufacture that gives us these miracle drugs, and yet our consumers are paying a disproportionate share of the cost of developing these drugs, and that concerns me, and it is the reason why I have cosponsored the chairman's bill.

But I think we should readily concede that that bill, important though it is, is not the answer to this problem. What we are really saying is that consumers should go to another country to get their pharmaceuticals or should be able to import them, and that really is not the full answer to this problem.

Indeed, an American consumer, a senior citizen in Maine who is having a difficult time affording \$300 worth of pharmaceuticals a month is probably going to have a difficult time affording \$250 in costs per month.

So I think we have got to remember that part of the solution to this is to reform Medicare to provide a prescription drug benefit if we are going to get to the real problem.

It is important, however, that we further understand the disparity in prices and try to come to some consensus on that issue as well, and in that regard, I would note that the United States apparently is the only industrialized country in the world that allows direct-to-consumer advertising on television and in print ads. The pharmaceutical industry is spending something in the neighborhood of \$2 billion a year on these ads. This is an issue that we have not discussed today but that we should look at, whether or not the FDA was prudent in allowing that direct-to-consumer advertising. There is no doubt that in some ways, that has made consumers better prepared to question their doctors about certain breakthrough pharmaceuticals, but on the other hand, \$2 billion a year going into advertisement concerns me, because I think that that is a significant cost driver as well.

Indeed, if you look at some of the statistics, they suggest that once the FDA lifted its rule and allowed direct-to-consumer advertising, that is when drug prices really shot upward, and that is when the disparity between the prices in Canada and the United States began to widen greatly, according to some reports that I have seen.

So I would suggest, Mr. Chairman, that we need to look at that issue as well, which we have not raised. I do not know whether either of our witnesses have a comment on the advertising issue or whether we should leave that to our panel of economists, but I do want to bring that up.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Kennedy?

Senator KENNEDY. Thank you, Mr. Chairman.

I want to thank you very much for holding this hearing today. It is enormously important, and I think our colleagues have pointed out why these hearings are necessary in regard to the questions of pricing and cost as well as the issue of availability of drugs.

I think it raises the fundamental issue that if we are able to do something about the pricing and the importation of drugs, we have the fundamental issue which Senator Collins has pointed out of coverage. This gets to the heart of our whole problem. One-third of our seniors have no insurance, and on the employer-sponsored, the total number is dropping like a stone. On HMO coverage, there are caps being increasingly put on by the HMOs at \$1,000 and \$500, which are causing our seniors to drop out.

Medigap is going through the ceiling, and the only group of seniors covered today is basically those on Medicaid.

But as you point out in this hearing, what has happened on prices and costs of drugs, the blue in this chart shows the CPI. So with the CPI at 2.5, 3.3, 1.7, 1.6, and 2.7 percent, we can see what has happened to drug costs.

As members have pointed out, we obviously have investments in new drugs and all the rest, but we have seen the explosion in costs, and many of the increases are "me-too" drugs, or drugs which have been on the market for a long period of time which have escalated in cost.

If you take that chart and put it against what the incomes of our elderly people are, you find that the average income for a senior is \$13,000, and the average age is 73, and 79 percent of our seniors are at incomes less than \$25,000. So when you talk about middle-income seniors, they are all hard-pressed in terms of trying to deal with these issues; very few of them are at the upper ends, so we have this enormous challenge.

The concern that I have, Mr. Chairman, is where we are going in the Congress. As we are meeting here today, the House of Representatives Ways and Means Committee is marking up a bill that was just introduced today, and they are marking it up tomorrow, and we can only see from the general outline the problems with this bill. It is an unusual way to request bipartisan support as well.

The concerns that I have on their particular legislation are that it leaves too many senior citizens out; it is too costly for the middle class; it provides second-class coverage for low-income citizens;

there are no defined benefits; and there is excessive reliance on private insurance. You are talking about the costs of advertising, the costs of middlemen, and the costs of profits. We debated that at the time we passed Medicare, and that is the reason we passed Medicare, and it is important that we have a Medicare benefit.

Let me just show two charts that illustrate the coverage and who is left out, Mr. Chairman. In this chart, under the proposal now before the Ways and Means Committee that will be marked up tomorrow, you will find that half of all those senior citizens are not even included. You have an existing 12 million who are not covered at all today—increasing numbers are not being covered, but you have 12 million who are not being covered—and only 6 million of those are going to be covered under the Republican proposal. That is number one.

The second chart shows the differentiation in terms of the costs. You will find under the Republican proposal that it is about \$1,275, and under the President's proposal, it is about \$575.

So the coverage will be inadequate, and the costs are still going to be exorbitant, and that really is a promise without a program.

I will just show these charts quickly. Based upon CBO assumptions, there would be no drug coverage at all under the Republican proposal—

The CHAIRMAN. Excuse me, Senator. This is the House proposal?

Senator KENNEDY. Yes, the Thomas proposal, the House Republican proposal. I will not ask you if you are a cosponsor of it at this time—

The CHAIRMAN. Please do.

Senator KENNEDY. There would be 12 million covered under the President's program; and the next chart shows the difference in terms of cost, which would be \$575 under the President's program and \$1,276 under the annual premium.

The point, Mr. Chairman, is that we want to make sure that when we have a drug benefit program, which is a concern of this committee—one, on price; two, on cost; and three, on coverage—that it will be worthy of the name. And I think we need one that is going to be worthy of the Medicare program, that it is going to be within Medicare, and that it is going to provide coverage for all, that it is going to be voluntary, that it will provide basic and catastrophic, and that it is going to be affordable. We should do no less.

I apologize for not having been here earlier, and I am grateful to our colleagues who made presentations here.

I thank the chair.

The CHAIRMAN. Again, we have two panels waiting, but I want to give every member an opportunity to speak at this time.

Senator Bingaman is next on my list.

Senator BINGAMAN. Thank you very much, Mr. Chairman.

Let me commend those who have already spoken.

This issue was brought to my attention last year. I grew up very near the Mexican border. I was with my father last year when he was going in to see a doctor, and the doctor prescribed Prilosec; he said my father should take a Prilosec every day for a while, and in sort of an offhand way, he said if you buy it here in this country, it will cost you about \$4 a pill, but if you buy it in Mexico, in

Juarez or Palomas, which are the two nearest towns to my home town, it will cost you about \$1 a day, or one-fourth of that.

So in response to Senator Frist's comment, I would just say that the doctor in this case had no concern about the safety of the product. There was no question that it was the same product; it was a question of whether you are going to pay \$4 per pill or \$1 per pill. And I am sure that most of the people who live in my State within easy driving distance of the border are given the same advice by their physicians—just go across the border, and you can save a lot of money. So the safety issue is really not an issue on the ground level for these physicians and these patients.

I would also just allude to this report which I guess was released today, entitled, "Prescription Drug Coverage and Rural Medicare Beneficiaries," put out by the National Economic Council. It makes an interesting point, where it says: "Rural beneficiaries pay over 25 percent more out-of-pocket for prescription drugs than urban beneficiaries."

So what we are really looking at, as I understand this report, is a substantial premium being charged to people who live in this country, and then you add about a 25 percent premium on top of that if you live in a rural part of this country, so the disparity becomes enormous.

I just say that to underscore what both of you have said.

I heard Senator Gorton's testimony about the Robinson-Patman Act application to this situation and how his bill would accomplish that, but I am unsure in my own mind how that would work if we were to try to apply the Robinson-Patman Act worldwide. I have just never heard that discussed. I do not know if either of you have had a chance to focus on that. I would favor whatever we can do to bring down the cost of prescription drugs. I cosponsored Senator Dorgan's bill and very strongly support it, to allow reimportation, but I am just unclear how the application of Robinson-Patman worldwide to the sale of drugs would work. That seems to me to be a substantially expanded application of that Act.

Do either of you have a thought on that?

Congressman Sanders?

Mr. SANDERS. Thank you, Senator.

I would agree with you, but a point that I think we have got to make is that our goal is not to force the people in Mexico, Canada, or Great Britain to pay higher prices for their prescription drugs. Our goal is to lower the price for the people in this country and make sure that we are equitably treated by an industry which last year made \$20 billion in profit, which spends far more money on advertising and so forth than they do on research and development.

Senator DORGAN. Let me make one point, and Mr. Chairman, I have to leave for another hearing, but I would just like to make one point on this.

I went to Emerson, Canada, which is 5 miles north of Pembina, ND, and in those 5 miles, there is an international border. The same drug and the same pill, made by the same company, inspected by the Food and Drug Administration of this country, costs double in many cases, in some cases, triple, and in some cases, 10 times as much in Pembina versus 5 miles north in Emerson.

So I repeat the challenge: Is there anybody who believes that that is justified?

My goal is not to force folks to leave this country to access prescription drugs. My goal is to force the repricing of those drugs in this country through global pricing. That is the mechanism. But what we have is a shroud, this law that says you cannot as a pharmacist or a distributor access those drugs and bring them back and pass the savings on to consumers in the United States, because we have an artificial barrier. So let us get rid of the artificial barrier, and as we do so, let us guarantee the safety and the chain of custody.

Senator Collins talked about miracle drugs, and let me say I want the pharmaceutical industry to be prosperous, I want them to do well, but I also want there to be some balance here in how all of this works. Miracle drugs can only perform miracles if someone can afford to take the drug they need for the condition they have. There are no miracles for people who are poor and cannot access these drugs. There is no miracle for the woman in Dickinson who is not taking the drug that will lessen her chances of recurrence of breast cancer, because she says, "I cannot afford it, and I just have to take my chances, therefore." There is no miracle for that woman.

So we need to provide access, and I want to force repricing in this country not through some artificial mechanism but just through access to the global marketplace, assuring the chain of custody and the safety of supply.

Mr. Chairman, thank you for holding the hearing, and I apologize for having to leave.

The CHAIRMAN. Senator Reed, I know you are going to introduce someone on the second panel. Would you like to talk now or wait until then?

Senator REED. Mr. Chairman, I will wait until the doctor joins us.

The CHAIRMAN. Thank you.

Senator Dodd?

Senator DODD. Thank you, Mr. Chairman.

I will ask unanimous consent to include an opening statement for the record, and I thank you for holding this hearing and for the witnesses that you have had before us this morning, our colleagues.

Like many people, I happen to believe that coverage is probably the best way to be approaching the issue of cost, and there are legitimate issues being raised about excessive cost to people. But I think coverage is more than likely the solution and the answer, because you obviously increase the buying power of a larger number of people, and in that way are more likely to naturally bring down prices than arbitrarily trying to fix a price, which can have huge unintended consequences and can get us into a morass of problems that we might not be able to extricate ourselves from.

There are all of these difference plans kicking around, but I hope we will not lose sight of the fact that that may be in the long-term, really, the best answer for us.

What seniors complain about is the cost to them, and obviously, with the kind of coverage that we are talking about here, you can reduce that cost to them substantially. That should not mean that

you are allowed to gouge a health care system, but I think there is a better chance of keeping the overall cost down.

Also, Mr. Chairman—and just having watched the testimony of some of my colleagues for a while in my office earlier—the drug industry is obviously an easy target because of this issue. But there are matters that we should be mindful of. I do not know how many people read the front page of our local paper this morning, but the headline reads “Microbes Winning War.” It goes on: “Microbes that cause diseases ranging from sore throats and pneumonia to malaria and AIDS are mutating at an alarming rate around the globe into much more dangerous infections that fail to respond to drugs, the World Health Organization warned.”

“We are literally in a race against time to bring levels of infectious disease down worldwide, before the disease wears the drugs down first.”

I bring that up only because it is critically important that we have a healthy, vibrant pharmaceutical industry. These products are not going to be made by the FDA, and with all due respect, I do not want to rely on foreign manufacturers and producers. We are enjoying a level of health and protection because we have the finest industry in the world in this country. I certainly take a back seat to no one in worrying about prices and gouging and what goes on there, but I also do not want to see us get into a situation where we come up with a solution that may be more harmful than the problem we are facing.

So I appreciate the testimony and look forward to a full hearing on how to approach this, but if we are going to deal with these problems like the headline this morning indicates, it will be done because we have smart, creative people and an industry that is vibrant and healthy and well; and I hope we do not lose sight of that in all this debate.

I thank the chair.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Mr. Chairman, thank you for holding this hearing and for your leadership on this important issue.

I know that my colleagues, particularly those on this committee, recognize the absolutely critical role that pharmaceutical products play in saving lives and improving the quality of life for all Americans. I am very proud of this committee's work in enacting the Food and Drug Administration Modernization Act of 1997, legislation which has been instrumental in making life-saving drugs and medical devices available to consumers more quickly, without compromising our high national standards for safety and effectiveness.

Unfortunately, too many of our senior citizens are not benefiting fully from the exciting advances in drug development. As we all know, Medicare does not provide coverage for prescription drugs—presenting a daunting financial barrier for seniors on fixed incomes. Nearly 13 million seniors or 35% of Medicare beneficiaries lack prescription drug coverage.

Regrettably, some of these seniors are forced to make the untenable choice of paying for their medicines or buying food. In a nation as prosperous as ours, this situation is unacceptable.

I first learned just how important this issue was to my constituents when I held a town hall meeting in Norwich in September 1998. The topic of the forum was the withdrawal of Medicare HMOs from the area. It became evident to me very quickly that the primary reason that seniors were so distraught about HMOs leaving was that the HMOs were taking their prescription drug coverage with them. The desperation of the individuals who spoke at that meeting was heartbreaking. They told HCFA and the insurance companies that they were willing to pay more, to forgo other benefits, if they could only keep their drug coverage.

I am extremely pleased that so many of my colleagues from both sides of the aisle are engaged in finding a solution to this problem—Senator Jeffords, Senator Dorgan, Senator Johnson, Senator Gorton, Rep. Sanders and others. I am also pleased that the Minority Leader has offered legislation, which I am cosponsoring, which also makes an important contribution to this debate.

I realize that in the end the final product will probably not look exactly like any of these proposals, but the fact that so many individuals across the political spectrum are thinking creatively about improving the access of seniors to lifesaving prescription drugs gives me hope that we will ultimately find a solution.

Again, I'm happy to see such interest in this issue. I look forward to working with my colleagues to ensure better access to prescribed medicines while retaining essential safeguards that save lives.

The CHAIRMAN. Thank you, Senator Dodd.

Senator Mikulski?

Senator MIKULSKI. Thank you very much, Mr. Chairman. I know the time is short, and I will ask unanimous consent that my entire statement be placed in the record.

The CHAIRMAN. Without objection.

Senator MIKULSKI. I would like to make just a couple of brief points.

First, this is probably the most significant issue that my constituents are contacting me about, and to them, it is a compelling human need. There are hundreds of letters and thousands of phone calls not only from seniors but from their families, who often have to subsidize them in order to be able to buy their prescription drugs.

An 84-year-old woman from the Eastern shore who is blind and diabetic tells me she takes 11 medicines every day and has to pay close to \$300 for those drugs out of an \$800 income.

The son of a 90-year-old woman, himself in his 70's, wrote me to say his mother spends one-third of her income on medications and now wants to take her medications every other day.

This should not be happening in the United States of America. When Medicare was created, it was to prevent family bankruptcy from hospitalization due to a catastrophic situation. It has worked well. Part B provided access to primary care. Now we have to go to a modern Medicare that helps move us to the management of chronic illness.

I find myself in alignment with the remarks made by the gentlelady from Maine with respect to innovation, access to innovation, and also some of her concerns about advertising. First of all, the gentlelady has been a real leader in increasing the funding for

research on diabetes at NIH. We are in alignment with that. We want innovation. Then we want access to innovation. Often, our constituents pay several times for innovation—they pay for it at NIH, they pay for it when it is value added, and they pay for it in their prescription drugs.

How can we have access to innovation and at the same time not stifle innovation?

Last but not at all least, I agree with the gentlelady's question about advertising. I think we have got to be very careful about price controls. I think we have got to be very careful about the unintended negative consequences. But I will tell you this advertising is really something. Again, I will come back to diabetes. I have seen more ads on glucophage, Avandia, telling you what it is, what it can do for you. People then run to their doctors because what is it that you want if you are insulin-resistant or diabetic—you want the latest. How do you find out what is the latest? Do you find out about it from a clinically-trained physician? No. You are getting advertising.

Well, we might be doing the slow dance to Viagra, but I think we have got to do a pretty fast step to find out what we can do about advertising and coming up with a prescription drug benefit.

Thank you, Mr. Chairman.

[The prepared statement of Senator Mikulski follows:]

PREPARED STATEMENT OF SENATOR MIKULSKI

Thank you Chairman Jeffords for convening the hearing today on the important subject of drug safety and pricing. It is a pleasure to be here.

One of the most important things I do as a United States Senator is listen to the people and the stories of their lives. And the problems people are having getting the medicines they need is something I've heard a lot about lately. In the last 6 months, I've gotten more than 200 letters and literally thousands of telephone calls from seniors and their families about the hardships that the high cost of prescription drugs and lack of insurance coverage are causing them. For example, an 84 year old woman from the Eastern Shore who is blind and has diabetes told me that she takes 11 medicines every day and is spending \$275 of her \$800 monthly income on prescription drugs. The son of a 91 year old woman wrote me to say that his mother spends one-third of her income on her medications, and often takes her daily medicine every other day to make it last longer.

This is simply unacceptable. Prescription medicines are now an essential part of modern medicine, and are an essential thread that must be woven into the safety net for seniors.

Many of my constituents also tell me they are paying much more for the same medicine as someone in Canada or Mexico, and they are outraged. I believe we must explore any and all avenues that help seniors—and all Americans—get the prescription medicines they need. That's why I am looking forward to learning more about legislation that would specifically address the issue of international drug disparities, both from its sponsors and its opponents.

But I also believe that we must deal with the issue of coverage. Too many Americans, especially older Americans, do not have cov-

erage for prescription drugs. Providing drug coverage for those who want and need it a great way to ensure access, and it is simply the right thing to do.

Thanks to the leadership of Senator Daschle, Senate Democrats have come together to agree on basic principles that should serve as a blueprint for action. We have agreed that a Medicare drug benefit should be:

1. Voluntary: Medicare beneficiaries who now have dependable, affordable prescription drug coverage should be able to stick with what they've got.

2. Accessible: A hallmark of Medicare is that all beneficiaries have access to dependable health care. The same should hold true of a prescription drug benefit.

3. Meaningful: A Medicare drug benefit should make a difference in the lives of seniors by helping protect them from excessive out-of-pocket costs.

4. Affordable: The benefit should be affordable both for beneficiaries and for the Medicare program. Medicare should contribute enough toward the prescription drug premium to make it affordable and attractive for all beneficiaries and to ensure the viability of the benefit. Low-income beneficiaries should receive extra help with prescription drug premiums and cost sharing.

I am proud to be a co-sponsor of legislation that puts these principles into practice. S. 2541 would create a new Medicare "Part D" for drug coverage beginning in 2002. Coverage would be voluntary and available to all Medicare beneficiaries. Medicare would cover half of beneficiary's drug costs up to \$5,000 when fully phased in, but it also would cover 11 catastrophic" prescription costs, meaning any out-of-pocket drug costs above \$3,000-\$4,000 would be taken care of by Medicare.

Many of the life-saving medicines that people count on are the result of American medical science and breakthroughs made in this country. I feel very strongly that all Americans should have access to those breakthroughs. We must act now to ensure that they do. Thank you.

The CHAIRMAN. Thank you, Senator Mikulski.

Senator Murray?

Senator MURRAY. Thank you, Mr. Chairman.

Obviously, this is a very hot and complex issue that we are trying to address and one that all of our constituents are very, very concerned about. I find myself wishing I could jump on a quick fix bill because it sounds great on a television spot or in the news, but I think we have to be very cautious in moving forward right now.

It is clear that a lot of prescription drugs appear to be cheaper in Canada. We have a lot of people with anecdotes about purchasing them cheaper in other countries, and I hear that concern from my own constituents, being a border State as well, and do believe we need to address that. But I am concerned, because being a border State, I also hear the other side of the story, where many drugs are not as available in Canada, and innovation is not as clear, and I hope we can move forward in a way that addresses the concerns of our constituents but does not stifle innovation or our ability to get drugs in this country as well.

We are here because prescription drugs are now a part of people's health care in a way they were not when the Medicare system was first established. People now have a quality of life, and they have the ability to be alive in many cases and to maintain better and healthier lives because of the prescription drugs that we have been able to produce in this country, and we want to make sure that that remains clear, and I think choice and the ability to be innovative is part of the American dream, and we want to make sure that remains there.

We also have to address the issue, and I think my colleagues have brought up a lot of really legitimate concerns in terms of price and accessibility, and I have come to the conclusion in my own mind that the quick fixes may not be what really produce the best results, and that is why I have focused my attention on the issue of Medicare and prescription drugs that we have been talking about under the MEND bill and other bills that are out there right now. I think that if we look at that and provide our seniors with a way to be a larger group of purchasers, that will address the price issue in the long run in a much better way.

I know we have to face the issue of younger generations as well and what they are paying for prescription drugs, and we will have to continue to focus on that, but I urge all of us to use caution in a very critical and important issue to many of our constituents.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. That is an excellent thought.

[The prepared statement of Senator Murray follows:]

PREPARED STATEMENT OF SENATOR MURRAY

As you know, I'm very concerned about making sure that all Americans have access to safe, effective, affordable medicines.

I'm also committed to making sure that American consumers still have a wide range of choices when it comes to their medical care and making sure they still have access to the innovative treatments that have brought dramatic gains to thousands of patients.

I believe we can find a responsible way to reduce drug costs, but the key word is "responsible." Any proposal must reflect the unique realities of our country's health care system—without jeopardizing access or innovation.

Mr. Chairman, I want to thank you for holding this important hearing, but at the same time, I am concerned that this debate distracts us from the more important issue of a Medicare prescription drug benefit. I want to encourage my colleagues to not lose sight of the need to provide Medicare beneficiaries with a prescription drug benefit.

The cost and availability of drug therapies are issues of great concern in my state. It was a major focus of several meetings I recently held in Seattle with consumers, insurance companies, providers and biotech representatives as we discussed a Medicare prescription drug benefit and, specifically, the Medicare Expansion for Needed Drugs Act.

Today, drug therapy treatments are as important to a patient's progress as hospital visits were 20 years ago. We know that high drug costs affect everyone—seniors, employers, insurance companies and individuals. Seniors are particularly hard-hit. They pay up

to 15% more for prescription drugs when compared to those under age 65 who are insured.

While we have heard a great deal about the cost of drugs, there has been little discussion about the savings realized—and potential savings provided—by new, innovative drug therapies.

We now have drug treatments that can prevent osteoporosis, the leading cause of hip fractures for women over 65. We can prevent the complete disability caused by rheumatoid arthritis. We can control high blood pressure and help prevent stroke and heart disease. We have drug therapies that can reduce cholesterol, which reduces the need for expensive bypass surgery. We can keep cancer patients healthier, and we can add years to survival rates for patients with breast or prostate cancer.

I believe that these innovative drugs offer great savings—both in terms of patients' health and also in terms of financial savings to our health care system and our overall economy. We should not overlook the savings that innovation brings us.

There are some who argue that we should impose price controls or that we should eliminate price differences between industrial countries. I wish it were that simple.

While the idea sounds politically attractive, I think everyone should realize what the possible consequences of such a "quick fix" could be—fewer choices—and less innovation.

We need to make sure that American consumers are willing to accept the restrictions on their choices that such a plan would impose.

Our recent experiences show us that Americans will not tolerate long delays in getting the innovative drugs they need.

Just look at the FDA Modernization process. This Committee spent well over two years working to enact the FDA Modernization Act to eliminate unnecessary and costly delays in approving new drugs and medical devices.

In 1992, this Committee, working with the industry, established a self-financing mechanism to ensure that the FDA had the resources necessary to meet the challenges of some rapidly developing biotech advances.

Our efforts were driven by the belief that lifesaving treatments should be available to patients as soon as their safety and effectiveness standards could be met. We provided for a new expedited review process and created a third-party review for certain medical devices to free up resources at FDA so there would be a greater focus on approving lifesaving devices.

We were motivated in our efforts by patients who were suffering and who demanded prompt FDA approval. In the end, we enacted a good, balanced modernization bill that has proven to be a lifesaver. American consumers would not tolerate unnecessary or bureaucratic delays in drug approval and availability.

Because drugs today are part of our overall health care delivery structure, it is difficult to isolate the cost of drugs when comparing our costs to other countries. We all know we have a very different structure in this country. Many countries provide universal coverage and access to all their citizens. Health care is treated like any other commodity in those countries. Costs are capped, access is limited, delays are expected and new innovative treatments are

not readily available. In many of these countries, a drug must not only be safe and effective, but must show immediate cost benefits as well. These countries have made significant sacrifices in consumer choices and access in order to achieve universal coverage to health care for all citizens. This is simply not the case in this country. To now say that we will use these countries as a model for determining drug costs or drug pricing fails to recognize the clear differences that exist.

American consumers would simply not tolerate the kind of delay and limited access that we see in other countries. I do not believe that American consumers should foot the complete bill for R&D, however, I am concerned about efforts to impose unreasonable price controls on drugs.

American consumers reap immediate rewards for the investment in R&D and safety. American consumers expect that drugs approved by FDA meet rigorous safety and effectiveness standards. FDA's primary mission is public health, and we expect no less. These factors and expectations must be considered when exploring the issue of drug pricing and costs.

While price controls or the ability to purchase drugs in other countries may appear to offer short term answers, our time would be better spent addressing the root problem: the lack of prescription drug benefit.

We must realize that our health care structure has dramatically changed in the last 20 years, and Medicare needs to be updated to reflect these changes. We can debate the merits of drug pricing and restrictive price controls, but at the end the day we have to modernize Medicare.

We know that one of the factors in determining the cost of a drug is what the market will bare. If we use the collective market power of seniors and the disabled, I feel confident that we can strike a better deal than what seniors currently receive.

I do think today's hearing will show us the complexity in drug pricing and drug costs. Simple solutions could have serious consequences for American consumers. We must ensure that these simple solutions do not hinder development of new innovative, life-saving drugs or delay access to these life saving drugs. We must ensure that these simple solutions do not jeopardize the health and safety of American consumers. We must remember that drug safety is not just about approving the drug therapy but the manufacturing and distribution criteria as well.

I do think there are reasonable steps we can take to address drug pricing and costs. I think the industry also must do more to spread the cost of drug development out over all consumers and must address the issue of direct consumer advertising. There is clearly a consumer benefit to direct communication about new innovative drugs, but I would ask if the industry gone too far and if it has resulted in an overutilization of drugs. These are areas where the industry must come to the table with solutions or it will face radical, irresponsible and arbitrary price controls. I also believe the industry must do more to educate consumers and providers on the overall savings from new drug therapies. Again, to simply look at drug costs without considering the overall impact these

drugs have on health care fails to recognize the changing role of drugs.

Mr. Chairman, again I want to thank you for scheduling this hearing, and I do hope that we will have the opportunity for additional hearings on these issues. I would anticipate the today's hearing will raise as many questions as it addresses.

I also want to welcome to the Committee Dr. Paul Abrams, CEO NeoRx from Seattle Washington. Dr. Abrams is here today representing the Biotechnology Industry Organization. NeoRx is a cutting-edge company engaged in research and development of cancer treatments. They are currently involved in a Phase III trial on a therapy that has shown real promise in treating multiple myeloma and will be starting a Phase I trial on prostate and breast cancer patients. This is a company that truly engages in lifesaving research and development. NeoRx is not a global company. It employs just 65 people, but it brings an important perspective to today's hearing. I welcome Dr. Abrams to the HELP Committee, and I thank him for his testimony.

The CHAIRMAN. Senator Reed, I will call on you now to introduce your witness or to make any comments.

Senator REED. Thank you, Mr. Chairman.

We will have the pleasure shortly to hear from Dr. Christopher Rhodes, who is professor of applied pharmaceutical sciences at the University of Rhode Island. The university has one of the foremost schools of pharmacy in the country, and Dr. Rhodes is a wonderful representative of the school.

He received his education at the Chelsea School of Pharmacy at the University of London, and later taught at Purdue. He is the author of many works in the area of pharmacy, and he is also president of PHARMACON, which is a private company which consults with the Government and industry on the formulation and analysis of drug products and procedures, and he has served as a consultant to the Internal Revenue Service, the United States Army Chemical Warfare Defense Command, and the Food and Drug Administration.

So when Dr. Rhodes joins us, we will be very enlightened by his presentation, and I thank him for being here today.

The CHAIRMAN. Dr. Rhodes, please come forward.

Senator WELLSTONE. Mr. Chairman, is Dr. Rhodes going to be testifying alone?

The CHAIRMAN. No. We are going to bring up the entire panel, but I was just calling on Senator Reed to introduce his witness.

Senator REED. I thank you, Mr. Chairman.

The CHAIRMAN. Also testifying this morning will be Professor Patricia M. Danzon, of The Wharton School of Management, University of Pennsylvania, where she is a professor of health care systems and insurance and risk management. Professor Danzon is recognized internationally as an expert in the fields of health care, pharmaceuticals, insurance, and liability systems. She has served as a consultant on international health care issues to the World Bank, the European Commission Working Group on Pharmaceuticals, the New Zealand Treasury, the Asian Development Bank, and the U.S. Agency for International Development.

Welcome, Professor Danzon.

Senator WELLSTONE. Mr. Chairman, could I introduce our Minnesota witness? I would like to give him a real Minnesota welcome.

The CHAIRMAN. Yes. You may introduce the next witness.

Senator WELLSTONE. He is not from Vermont, and I do not want him slighted in any way.

I am pleased to welcome a very distinguished witness from Minnesota, Dr. Stephen Schondelmeyer, who holds a doctor of pharmacy and a doctorate in administration and social services. He is director of the PRIME Institute of the University of Minnesota; head of the Department of Pharmaceutical Care and Health Systems; professor of pharmaceutical economics; and he holds an endowed chair in pharmaceutical management and economics.

As director of the PRIME Institute, Dr. Schondelmeyer directs research, education, and consulting on economic and policy issues related to improving access to the population to pharmaceuticals and pharmaceutical services. He is considered a national expert—really, an international expert—on this issue.

Most important of all, he has a wonderful heart and soul. I have seen him at many community meetings in Minnesota, and he gives his time and his expertise to people and communities over and over again.

Thank you for being here, Dr. Schondelmeyer.

The CHAIRMAN. Dr. Rhodes, please proceed.

STATEMENTS OF CHRISTOPHER T. RHODES, PROFESSOR OF APPLIED PHARMACEUTICAL SCIENCES, UNIVERSITY OF RHODE ISLAND, KINGSTON, RI; PATRICIA M. DANZON, CELIA MOH PROFESSOR, THE WHARTON SCHOOL OF MANAGEMENT, UNIVERSITY OF PENNSYLVANIA, PHILADELPHIA, PA; AND STEPHEN W. SCHONDELMAYER, HEAD, DEPARTMENT OF PHARMACEUTICAL CARE AND HEALTH SYSTEMS, PROFESSOR OF PHARMACEUTICAL ECONOMICS, AND DIRECTOR, PRIME INSTITUTE, COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Mr. RHODES. Thank you very much indeed, Mr. Chairman. It is a great privilege to be here, and it is a very great privilege to have those very kind words from the Senator from the Ocean State.

What I am going to say today is basically concerned with the technical and scientific side rather than the economic side.

I have served on the United States Pharmacopoeia Committee of Revision, that is, USP; I have also served on two FDA advisory committees. I think that the United States public can justly be very satisfied in a general way with the quality of drug products which they receive. There is no doubt in my mind that the FDA is probably the preeminent regulatory authority in the world. I am also quite convinced that the United States Pharmacopoeia, USP, which is the body recognized by the U.S. Congress and some 30 foreign countries as providing standards for drug substances, drug products, and test methods, is again probably the best Pharmacopoeia in the world.

The third element that is essential in controlling the quality of drug products in the United States is the fact that over the last 20 years, I for one have seen a great increase in the standards used in QC/QA, that is, quality control/quality assurance, labs, and so in

general, I have to say that I think this triumvirate is working very well together.

Now, within the international community, there are two very important tendencies that have already been referred to to some extent in previous testimony. They are globalization, which has been mentioned, and harmonization, which I do not think has been mentioned.

We all know what globalization is. It is that more and more companies are becoming what I call supra-national rather than national, and in the pharmaceutical industry, one of the companies I used to work for was originally a small British company, Beecham; it then became part of SmithKline Beecham, then Glaxo, Burroughs Wellcome, and so on. They now have many supra-national companies like that, and we are probably going to see more of them, which operate in different countries, but they try to standardize their formulation, their method of manufacture, and so on. This is a very important element when we consider reimportation of drugs into the United States or if we look at another aspect that has been touched upon, and that is straight importation from foreign countries.

The other important element internationally within the pharmaceutical world is harmonization. Some years ago, we set up the International Conference on Harmonization, ICH, and the three big pharmaceutical powers—the European Union, the United States, and Japan—are the movers in that group. In ICH, we are gradually moving toward a situation in which all drug products will be approved by the same process, the same standards, and the same tests throughout the world. We have not gotten there yet, but in some areas, as for example, drug product stability and shelf-life, we do have harmonization. So I think that is a very important background to the reimportation of drugs.

A proposal to allow the reimportation of prescription drugs quite naturally raises concerns about possible quality defects of such products. It would be have to State that such products could never have any problems. Indeed, we know that even with nonreimported products, problems do occasionally occur, and recall of unsatisfactory product is required, and also as standards for safety and efficacy are continually evolving.

Just one quick example. A couple of years ago, USP carried out a study on what happens to drug products when they are shipped by mail order. They came up with their mailbox study which showed some very worrisome results, that some products are left in mailboxes where the temperature reaches over 130 degrees Fahrenheit—hotter than the water coming out of our showers—for 8 to 10 hours, and the effect on some drugs could be very serious indeed.

As a result of that study, both USP and FDA are now focusing more attention on the quality of drug in the channel of distribution. I make that point to emphasize that although I think our system here in the United States is very good, it is not perfect, it is still developing.

Internationally, a great deal of concern has been addressed about counterfeit drugs. Gentamicin was mentioned earlier this morning. I would point out to the committee that there is now the Perma-

nent Forum on International Pharmaceutical Crime, which is addressing this matter. But for reimported drugs, drugs that have been made in the United States or in Canada, drugs which meet all relevant standards of USP, drugs which have been manufactured in facilities that have been inspected by FDA, and such facilities meet all relevant current, good manufacturing practice standards, I can see no problem whatsoever, as long as there is an appropriate paper trail—that has been touched on earlier—and as long as the time lag caused by reimportation is not substantial, and in most instances, drug products that we are talking about have a shelf-life of 3 years, and it would be a very slow train indeed that took 3 years to take drug up to Canada and back in that period of time.

So for most reimportation, I think a paper trail would be sufficient. However, I do understand that there will be cases when drug will be imported into this country which does not meet those criteria I just mentioned. In those instances, I have every faith in the ability of FDA, working in concert, perhaps, with USP, to develop appropriate laboratory tests which could be performed relatively inexpensively in order to have a safety, a second safety net, upon the quality of these drugs products.

Now, I am sure the question will come up who is going to pay for it. I am not an expert on paying—I merely tell people what to do rather than how to pay for it—but perhaps the user fee concept that has been so successful at FDA could be considered in this regard.

In conclusion, it is my considered professional opinion that the process of using reimported prescription drugs in the United States need not place the American public at any increased risk of ineffective or dangerous products. I further believe that USP and FDA do possess the necessary personnel, equipment, and expertise so that if necessary, samples could be appropriately evaluated.

Thank you very much indeed, Mr. Chairman.

The CHAIRMAN. Thank you, Dr. Rhodes.

[The prepared statement of Mr. Rhodes may be found in additional material.]

The CHAIRMAN. Our next witness is Patricia Danzon.

Ms. Danzon, please proceed.

Ms. DANZON. Thank you, Mr. Chairman.

I appreciate the opportunity to be here today. I am going to speak about the economic issues involved based on my research on price differences and on the effects of importation for pharmaceuticals.

Most studies of cross-national price differences for pharmaceuticals have led to the consensus view that we have had here today, that there are vast differences between prices in the United States and in other countries.

It is true that many brand name products do have lower prices in Canada and other countries than in the U.S. But it is not correct to infer from these studies that on average, prices in the U.S. are much higher than in other countries. The studies that we have heard about are based on flawed methodology. They are based on very small samples of leading branded products; they leave out generics, which account for over 40 percent of prescriptions in the

U.S.; they calculate simple averages without weighting products to reflect the relative importance of different products in the overall market basket. So they are violating the basic methods that the Bureau of Labor Statistics and statistical agencies in every country use for doing basic price comparisons.

When the comparisons are done at the retail level, they factor in margins for wholesalers and pharmacists as well, and none of the studies takes into account the discounts that manufacturers give to managed care companies and to the Federal purchasers.

The study that I have done of international price differences was able to look at prices in seven countries, including a comprehensive market basket of products. We were able to include all matching compounds, including all dosage forms and strengths, and calculate price per dose and price per gram. The results of that study are appended to my written testimony.

Just to summarize, what we found was that prices on average were higher in Canada, Germany, Sweden, and Switzerland; prices were lower in France, Italy, Japan, and the UK. But in all cases, the differences were smaller than we have heard from these other studies.

Although my study was based on 1992 prices, so the differences today may be different, nevertheless the general conclusion holds that valid price comparisons must be based on representative samples and use standard index number methods such as those used by statistical agencies such as the Bureau of Labor Statistics.

Turning now to factors that contribute to the differences, first, it is important to point out that health care systems in different countries are very different. Prices of physician services and hospital services are also much lower in other countries. But sticking with pharmaceuticals, for developing countries, the big price differences reflect differences in income levels, differences in intellectual property protection—there are a number of copy products—lower-quality manufacturing standards.

For industrialized countries, the main factor leading to differences is regulation, systems with price and volume and expenditure regulation.

The third factor leading to differences is the type of measurement error I mentioned earlier, that when we do these comparisons, we do not include on the U.S. side the discounts that are given to manufacturers and to Government purchasers, so the differences tend to be exaggerated.

Moving on now to the proposals for importation and likely effects, I think it is very important to distinguish between short-run effects which apply to the products that have already been developed and are already on the market and longer-run effects. For the short-run effects, it is true that in the short run, importers would be able to obtain products cheaper. There is no guarantee that those lower prices would be passed on to consumers. Indeed, when you look at experience in the European Union, which does permit trade within the European Union—not importation from outside the EU, but within the EU, so-called parallel trade is permitted—their experience is that lower prices are not necessarily passed on to the final consumers.

However, leaving that aside, one reason that trade is not permitted from outside the EU is that that would be a fundamental change of patent rights. Patent rights traditionally permit the patent-holder to bar trade in the patented product, importation by other third parties into a particular country.

Why is trade in pharmaceuticals not just like trade in any other product? For one thing, there is the patent issue; but second, generally, trade is beneficial because prices are lower in other countries because they truly have lower costs. In the case of pharmaceuticals, as we have said, many of the lower price are not reflecting lower costs, they are simply reflecting greater leverage of regulatory authority. It is not that they truly have lower costs.

Now, if these lower prices are imported into the U.S., that will undermine the ability of pharmaceutical companies to cover their joint costs, because in understanding what is going on here, it is really important to understand the cost structure of the pharmaceutical industry. R and D accounts for about 30 percent of total costs once one factors in the opportunity cost of the funds during the long R and D phase—12 years or more. Taking that into account, R and D is about 30 percent of total cost. These costs are a global cost; in other words, they are a joint cost of serving consumers in every country.

The actual marginal cost of producing and distributing a product in any country is quite low, so aggressive regulators can force prices down to marginal cost, but if everybody pays marginal cost, nobody will pay for the fixed cost, and there will be no incentive for R and D.

There is certainly some free-riding that goes on in other countries of trying to pay only marginal cost, but does that mean that we should move to a system of uniform pricing, trying to import these foreign prices from abroad? I would argue no, that on the contrary, the economic theory of trying to pay for these common costs, which occur in many other industries—they occur in airlines, in hotels, etc. The best way of paying for these common costs is to permit price differences, with different consumers paying different prices based on their income levels and their true price sensitivity. So moving to a system of common prices will in fact result in higher prices for consumers overseas, in which case they will consume less. That is real hardship to them, and they will thereby, because they are consuming less, actually contribute less to R and D in this country. It will not benefit U.S. consumers in the longer run, because if foreign consumption is down, then we would have to pay higher prices to support the same level of R and D.

So overall in an industry such as pharmaceuticals that has a high component of common costs, permitting price differentials is the best way of financing that common cost.

Turning to the real problem, which is one of affordability for both seniors and others who do not have access to coverage in the U.S., the best way of dealing with that, I believe, is to get everybody into competitive plans. The fact that there are price differences within the U.S. market is evidence that competition can work to constrain prices. Managed care plans, PBMs, to obtain significant discounts, and if we can obtain those sorts of discounts for everybody, then we would be encouraging a system that both makes coverage af-

fordable for everybody but also preserves incentives for R and D and therefore for the production of drugs in the longer run.

Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Ms. Danzon may be found in additional material.]

The CHAIRMAN. Dr. Schondelmeyer?

Mr. SCHONDELMAYER. Thank you, Senator Jeffords, and thank you to your colleagues.

I am pleased to be here today to talk about drug prices, imports, and safety issues. These are but a small part of a much bigger picture of the valuable drugs that are necessary in our society.

I would like to start by pointing out that drugs really are essential to life and health. I would ask how many people in this room have never used or needed a prescription drug. Any time I go to talk to senior groups, I ask how many in the room have never used a prescription drug, and rarely do I have anybody raise his or her hand. That tells us that prescription drugs are in universal demand. Everybody needs them.

Prescription drugs are also essential to life and health, and I would argue they are an essential good in our society, a good that is special and deserves treatment above and beyond just the sale of bluejeans or other things in our society.

Let me start my comments by doing the obligatory discussion of increased prices and other things. First of all, the Consumer Price Index, as was pointed out earlier by one of our Senators, has gone up at about 2.2 percent in 1999 for all items, but for prescription drugs, it went up 5.7 percent, and actually, in December 1999, the prescription drug inflation rate was up to 6.1 percent. So we are seeing prescription drug inflation begin to climb again and climb substantially.

Not only is the price going up, but the utilization, the number and types of drugs are going up. In some cases, that is good. We have people being treated for diseases that had never been treated before, but in other cases, it may be overuse stimulated by all of these wonderful ads that we see on TV—they create some good, but they also create some harm and adverse consequences, and we need to evaluate and take into account the effect of those increased costs.

Also, I would remind us that prescription drug expenditures have been going up at double-digit rates for the last 5 years, and this is not just under the Medicaid program; this is in every private health insurance program in the country. I have had calls from major Fortune 500 countries around the U.S., asking how do I manage my drug benefit program. I cannot afford a 15, 18, 20 percent increase in drug expenditures every year. These are Fortune 500 major companies. These are not Joe's factory down the street. Even our major corporations are struggling with the increasing expenditures under prescription drugs, and they need help.

Next, we can turn to the issue of where does pricing fit in. I appreciate the insights provide by my colleague, Professor Danzon. She described many of the factors that need to be taken into account to do one particular type of study of prices, and that would be a study of what is the net manufacturer price for all products

in the market to all buyers within society, without taking into account the differential effect on individual consumers and the distributional effects of some people being winners and some people being losers.

But there are other questions that we can ask about pricing and address in different ways. We can ask what is the price from the same manufacturer to different customers in the same country or in different countries. We can ask what are the adverse consequences of price differences in the marketplace; who are the winners, who are the losers—yes, there are losers. There are people who have consequences from high prices, people who have illnesses that continue and get worse and have ill health effects and ill economic effects.

We can also ask what is the impact of manufacturer pricing practices on a price-sensitive elderly patient with limited resources, paying cash for his or her own prescriptions. This is very relevant to the debate today on Medicare. I talk to many senior citizen groups, and I am always incensed when I hear people saying, well, the price-sensitive buyers are getting better prices, and those who are paying higher prices are not price-sensitive.

I challenge you to show me a senior citizen who is not price-sensitive. Yet these senior citizens who pay out-of-pocket for their own prescriptions are paying the highest price, not just in the United States, but the highest price in the world. Yet they are very price-sensitive, but market mechanisms—the structure of this market has shut them out from having access to those lower prices.

So we have to be careful how we use our economic terms. I understand in a macroeconomic sense how this works, but macroeconomics is really built upon fundamentals of microeconomics. That means one individual at a time making decisions, and the prescription drug market is a market where individuals make decisions one at a time, and every citizen is involved.

We have seen how there are different prices around the world. In the U.S., it may be \$1 per tablet, and it may be 65 cents in Canada, 60 cents in England, and lower prices in other countries, Spain and elsewhere. Imagine for a moment that we are starting with those differential prices. What has happened just in the last year in the other major countries around the world?

I surveyed Scripps, which is one of the industry newsletters, and this is what I found. I found that in Canada, the price of branded drugs went down about three-tenths of a percent last year; in the United Kingdom, they implemented a price cut of 4.5 percent; in Germany, a price cut of 5 percent; in France, a price cut of 5 percent; in Spain, a price cut of 6 percent; in Portugal, a price cut of 5 percent; in Netherlands, a 3 percent decrease; in Japan, a price cut of 7 percent. All the major industrial countries around the world are somehow dealing with and cutting drug prices.

Now, I am not here to say that we should implement price controls, that we should go in and begin carving away at the prices of the industry. But all the rest of the world is squeezing that big balloon, and it is bulging out here in the U.S. as our prices continue to go up.

Actually, I can illustrate that another way. In reading these newsletters, I saw that the head of one of the major pharma-

ceutical companies based in Europe has said that his company's goal is by the year 2004 to have 40 percent of their sales coming from the U.S. market, and in order to do that in the next 4 years, they would have to achieve sales increases of 26 or 27 percent a year in the U.S. So they have targeted growing their market by 26 or 27 percent in the next 4 years here in the U.S. They have a few new drugs coming along, but not enough to sustain a 26 or 27 percent increase, so that signals to me that a lot of that increase from that European pharmaceutical company is going to come from prices, and it is going to come in the U.S. marketplace, and we are going to pay that cost.

I then looked at what do we know about the cost structure of what goes into \$1 per tablet when we buy a tablet. If that tablet costs \$1 per tablet in the U.S. and 65 cents in England, I compared with England. First of all, what we know is that the actual cost of production, producing the tablet, is about the same, no matter—in fact, often, the product is made in Puerto Rico, and it is shipped to England and shipped to the U.S. and shipped to Canada and shipped to Mexico, and shipped to everywhere. So the cost of production is about the same. On research and development, in England, they spend about the same percentage of revenue on research and development—remember, we are spending 20 percent of \$1 per tablet, and they are spending 20 percent of 65 cents per tablet. So they are paying less for less research in that way.

Also, there are similar percentages for net profit. That is, in the U.S., companies average 18, 20 percent net profit, and 18, 20 percent in England. But again, it is 18 percent of \$1 and 18 percent of 65 cents.

But the area where there is the greatest difference is in marketing and advertising. In most European countries, they limit the amount of revenue or expense that can be charged off against marketing, advertising and administrative costs in calculating the profits or prices that they will negotiate with drug companies. So what we find is information that would suggest that we spend about 30 percent of the average dollar on prescription drugs in the U.S. on marketing and advertising—so that is 30 cents out of that dollar—and in England, they spend about 9 or 10 or 11 percent of that 65 cents, so 10 percent of a 65-cent drug is going to be 6.5 cents versus the 30 cents that we spend in the U.S.

Now, how many of those senior citizens who are having trouble paying for their prescription drugs intended to finance to the tune of 30 percent of their drug costs advertising campaigns, and how many of them got better because of those advertising campaigns? Did the drug work any better for that patient who was already on that medication because of that advertising campaign? I think not.

I would argue that the major factor driving the difference in pricing is marketing and advertising, not research and development, not profits, not cost of production, but marketing and advertising.

I am all for some marketing and advertising, but I think we have gone way overboard, and it is time we back up and reexamine the role of marketing and advertising. There is no other country in the world that allows direct-to-consumer advertising; that should tell us something. Sometimes we are ahead of the curve, but sometimes we get so far ahead, we get behind the curve.

I do think that parallel imports, allowing imports from other countries, countries that we have confidence in—countries that we have dealt with on the harmonization issues, and we understand how their FDA-type agency works—we can have confidence in them.

I agree that we have the best FDA system in the world, but even our current system allows some product in the U.S. market that is problematic or counterfeit or that has problems. We need to work on it, and we need to work on putting the control and power and authority in our FDA not just in the hands of the manufacturers, but balancing that so that consumers' interests are served by the FDA.

Last time I looked at the legislation, I think FDA was a consumer agency. But often, their actions do not look like that; they look like they are defending and serving only the industry. I want them to serve the industry and be very collaborative with the pharmaceutical industry, but they also need to serve the interests of individual consumers.

That will bring me to my last point. I look at safety from a slightly different perspective, and others have commented similarly, but I would argue that a drug that a person cannot afford is neither safe nor effective. I would argue that far more economic harm occurs in this country today to senior citizens who cannot afford their medications than ever occurred prior to or after the Prescription Drug Marketing Act from counterfeit drugs coming into the U.S.

I would not say let us pass a law that knowingly allows bad product in the U.S.—no. I would say let us look for ways to work with FDA in our sister countries to import good, high-quality drugs that meet the same standards we are used to in the U.S. But I think we must explore ways to develop parallel imports and begin to bring competition and free trade, as we have talked about, into this marketplace.

I would argue that a senior citizen who does not obtain his or her drugs has far more risk of harm than of ever getting hold of a counterfeit or bad-quality drug product in the United States.

One of the Senators commented that one of her constituents was going to cut her drug use in half and only take half of it. Every time I talk to senior citizens, I remind them that almost every drug I am aware of, when used at half its normal dose, has absolutely no effect, so you are wasting all of it rather than spreading it out. This is not the position we should be putting our senior citizens in within the United States.

Let me close by telling you that I want our pharmaceutical industry to be innovative, successful, profitable, and we have evidence from Fortune 500 and other sources that they are in fact the most profitable industry in the United States. In fact, if you look at their profit margins compared to other industries, pharmaceuticals could lose one-fourth of their profits and still be America's most profitable industry.

If you look at their profit margins over time, after the Hatch-Waxman Act allowed freer access to generics, after OBRA-90 required Medicaid rebates, their profits keep going up; their expenditures on R and D keep going up. We were told as both of those

pieces of legislation were being debated that this will hurt our profits, this will hurt R and D, this will destroy the industry. Neither of those pieces of legislation destroyed the industry. Neither of them cut back on the R and D that we spend in this country, and neither of them damaged the profits of this industry.

So I think we have to look at history, look at the examples we have from the past, and ask ourselves how can we work with this industry to find a meaningful way to arrive at truly market-based prices in this country.

While there may be consequences from the adoption of some new way of dealing with prices and coverage of drugs, I would argue that there are far more consequences from sitting on the side and not dealing with it.

Thank you.

The CHAIRMAN. I thank all three of you for very helpful testimony.

Dr. Rhodes, in your testimony, you mentioned that USP's recent mailbox study showed that some products undergo temperatures of 120 degrees for a number of hours. Can you explain why this is cause for concern and whether these concerns vary with different products?

Mr. RHODES. Yes, indeed, it will vary. There are some products where 130 degrees would have no harmful effect. There are other products—I am thinking particularly of things like protein drugs, insulin, and so on—where 130 degrees is a very high temperature, and even for a few hours, there is good reason to believe that the therapeutic efficacy would be greatly affected.

I do not want to scare anyone, but I mention this as an example of USP and FDA looking at the situation in the U.S. and seeing there is still room for improvement. This is what both FDA and USP are doing, and they are now giving more attention to the quality of drug in what are called the channels of distribution.

The CHAIRMAN. Dr. Danzon, you mentioned that the European Union permits so-called parallel trade within the EU. Can you explain to the committee how parallel trade compares to what we are calling reimportation, and does this practice tend to equalize prices on eligible products within the EU, and where is it permitted?

Ms. DANZON. As I understand the proposal here, yes, it is the same as parallel trade within the EU. It would permit the importation of products from other countries. My point was that the European Union has decided to permit that only within countries within the EU which are part of the economic community, but does not permit importation of products from countries outside the EU. So in that regard, it would be different from a proposal here that would permit blanket importation from any other country.

As to whether or not it has brought about uniform prices, there are no good studies of this, and it differs across products. There is more trade in the larger products where the volume is sufficient to cover the cost to the wholesalers of getting into the business. It has certainly on average tended to narrow the range of prices in different countries, and it makes companies try to move to a system of launching products at a uniform price in all countries so that price differences will not simply be arbitrated away by wholesalers.

The CHAIRMAN. Dr. Rhodes, you mentioned that the International Conference on Harmonization is making progress toward a uniform approach to evaluating the quality of drug products. Can you explain more about the uniform approach and how far you think we are from such an approach?

Mr. RHODES. The idea is that eventually, if I wanted to market a new drug substance in the United States, and I wanted to market the same new drug substance let us say in Japan, the studies I would do in the U.S. would be identical to those that would be acceptable in Japan and that we would have exactly the same test methods, we would evaluate the data in exactly the same way so that worldwide, there would be one standard for drug products.

You, sir, know how hard it is to get agreement with people from 50 States of this Union. You will no doubt understand that getting harmonization just between the big three powers has not been easy. We have made progress, as I mentioned, on drug product stability; we have already gotten an agreed document; we have agreement on clinical trials, and I am quite confident that within, say, 10 years, the standard for drug products will be almost identical, including labeling.

At the moment, certainly, if you look at the quality of drugs produced in the European Union—I do not know so much about Japan—I have every confidence in, for example, the quality of material produced in Germany. I think that on average, it is just as good as it is here.

So to answer your question, harmonization is taking time. I think that for all intents and purposes, it may be completely done within 10 years or so.

The CHAIRMAN. Dr. Danzon, you mentioned that although free trade usually benefits consumers, in the case of trade in pharmaceuticals, the savings may accrue largely to the pharmacist or the wholesaler. Wouldn't competition between many pharmacists and wholesalers keep their markups to a minimum, thus passing most of the savings on to the consumer?

Ms. DANZON. It certainly depends on the degree of competition, particularly in the retail pharmacy market. My main point, though, about why trade in pharmaceuticals is different from trade in other products has to do with two facts—that pharmaceuticals have a high ratio of fixed costs relative to marginal costs and that overseas, regulation has an incentive to try to force prices down to marginal cost.

So if we end up importing prices that are set to be only sufficient to cover the marginal costs, overall, the fixed costs are not covered, and that clearly is a strong disincentive to R and D. That is the main reason for considering trade in pharmaceuticals to be a different issue from trade in lettuce or other products that do not require a very significant R and D input before they come to market.

The CHAIRMAN. Senator Frist?

Senator FRIST. Thank you, Mr. Chairman, and I thank all three panelists for their testimony—excellent written testimony as well as their presentations—on a range of issues that reflect the difficulty in terms of applying competition in the marketplace to the pharmaceutical and prescription drug market.

Yesterday, I was in Tennessee at a town meeting with about 60 or 70 senior citizens in a rural county, Jefferson County, in the community of Dandridge. In a town meeting, you can really explore with a group of people about the size of this room how they pay for prescription drugs, their satisfaction, roughly how many drugs they are on. And it is amazing—if you did the same exercise 10 years ago, most people would say they were on one prescription drug, but now, when you ask them to raise their hands, people are on six or seven prescription drugs in a roomful of 70- and 75-year-olds. And it is miraculous. I heard testimony from one woman who stood up and said, “I had not been out of bed in 2 years, and now, through a shot twice a week, I am up and walking around.” You hear that kind of testimony, and it shows the miraculous advances that are being made.

How much does it cost? It costs probably \$8,000 or \$9,000 a year for that one drug. But it shows the challenge that we all have as we go forward.

One exercise that I did in the group that is really underscored, I think, by some of the comments today, or allows me to illustrate it, was when I asked who was satisfied with how much they are spending on prescription drugs. And the three groups were basically those in an element of managed care, prescription drugs being part of a larger plan, fairly seamless—they did not really separate in their minds the use of prescription drugs versus going into the hospital or getting a preventive test, and for prescription drugs, it was a nonissue. They were able to get the drugs—yes, they had to pay a copayment, but it was part of this seamless care.

The next group had the Medigap, the freestanding drug policies, and they were pretty satisfied. Two out of three in the room, which is the nationwide statistic, did have some coverage, but they say it is expensive. “I got my drugs; I am on all five that my doctor is recommending, but it is costing me a lot.”

The third group were that one-third of those people who really were not on as many prescription drugs—maybe they did not need them, or maybe they just could not afford them—who would go into the retail pharmacy and pay \$50 for something that if they were part of a plan would have cost them \$5 or \$6.

It drove home to me the importance of having seamless coverage where prescription drugs are a part of overall health care, which I contend we have to move to in this country, and with John Breau, I am working on that as part of a Breau-Frist Medicare plan.

My question to all three of you is if we did take 33 million Americans, seniors, and 5 million individuals with disabilities, and we gave them access to an insurance-type model health care and prescription drug plan, how much—and again, this is really rough—would the overall cost of prescription drugs fall just by having people enrolled in an element of prescription drug coverage where obviously there is buying power—where instead of having the woman yesterday who walks three blocks to the pharmacy and puts cash on the table and is subsidizing the 30 percent of the common cost of the research and development in this country and subsidizing the rest of the world; it is that senior—if we offered to put them into a larger-type insurance pool, what would just that alone do to

the cost of prescription drugs in this country, roughly? Would it go down? Would it go down 10 percent, 20 percent, 30 percent? I will throw that out to all three of you.

Dr. Danzon?

Ms. DANZON. It would certainly go down. The evidence on what the effects of PBMs, pharmacy benefit management companies, is on the overall cost of drugs varies, because it depends on how aggressive the PBM plan is. You can have a restrictive one or a more comprehensive one.

But in general, there are savings both from the discounts with manufacturers, so discounts on the products, and then there are savings because of discounts on the dispensing fees that are paid to pharmacists. In addition to the cost savings, there are improvements in the quality of care, because as part of the managed drug benefit, you have drug utilization review, you have greater convenience for the consumer, because when they go to the pharmacy, there is immediate checking on eligibility of coverage and where there are interactions with other products that they are taking, so there is a quality control as well as the cost reduction.

Senator FRIST. Thank you.

Dr. Rhodes, or Dr. Schondelmeyer?

Mr. SCHONDELMAYER. I think first of all, it depends on what we mean by what will happen to the cost. If by "cost," we mean how much we spend totally, the total expenditure, it will go up, because what we know is that when you make something available, subsidized, to a population of people, they use more of it; and using more may be appropriate for most drugs. These may be people who need medications but cannot get them now, and that is what we talked about.

So I think first of all, we would see a substantial increase in overall utilization among the elderly, much of which is appropriate and necessary. Some would be unnecessary, and we need to try to prevent against that.

Second, many people have argued that the volume of increase in utilization that would occur even if we applied Medicaid-type rebate discount requirements would still result in increased net revenue and profit to the pharmaceutical companies because all of this increased volume would be at the marginal cost, not something that drug companies had planned on or counted on to take care of all of these sunk costs that they have already incurred, because none of them has anticipated to this point having a Medicare coverage of prescription drugs, and most probably do not think they will have one next year.

So I would argue that it is marginal cost pricing, and so industry would gain in both revenue and profit from that.

I think, though, that the critical issue here is what do you do in terms of total coverage. Are we talking about just up to \$500, \$2000? Are we talking about true stop-loss, catastrophic coverage or not? That will affect what I think the real net bottom line is.

I think that what is most critical for American seniors, even though they will say they want lower prices on the first-dollar drug, is that fear that if I get cancer, or if I get a disease that requires a \$30,000-a-year drug, I cannot afford it. And if all we pass is a plan that covers \$2,000 or \$3,000 a year in drugs—which will

help; I do not argue that—but that does not solve the real fear that most seniors have—how do I afford that major catastrophic illness that can use one of these miracle drugs.

Senator FRIST. Thank you.

Dr. Rhodes, just briefly, please.

Mr. RHODES. I do not think I can add anything useful, sir.

Senator FRIST. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Collins?

Senator COLLINS. Thank you very much, Mr. Chairman, and I want to thank all of our witnesses for giving a very interesting perspective on this problem.

Dr. Schondelmeyer, I was very interested in your comments in particular about the impact of direct-to-consumer advertising on the costs of prescription drugs, and particularly the comparison that you gave us between the United States and Great Britain—I think it was 30 percent versus 6 or 7 percent of the cost of the pharmaceutical was due to the advertising costs. Similarly, the National Institute for Health Care Management has found that the 10 most heavily advertised drugs have been responsible for 22 percent of the increase in total prescription drug spending in the last 7 years. I think that is a very startling statistic, that just 10 pharmaceuticals, but the 10 most heavily advertised, have been responsible for 22 percent of the increase.

Have you done any research or are you familiar with any research that has looked at the impact of the change in the FDA's policy, lifting the prohibition on direct-to-consumer advertising and the spiraling increase of pharmaceuticals? Is there a difference between when the FDA did not allow direct-to-consumer advertising and our experience now with direct-to-consumer advertising with regard to the impact on cost?

Mr. SCHONDELMAYER. To my knowledge, there is not a well-defined definitive study that has been done yet. I am doing some work on my own on the Medicaid expenditures and how much of the Medicaid expenditures—and I am looking at a period before the direct-to-consumer advertising and a period after it; how much of the rapid growth in Medicaid expenditures has come from the drugs that have direct-to-consumer advertising—I am in the middle of that process, but I would tell you that the evidence so far is that it is every bit as strong as what was found in the National Institute of Health Care Management study and maybe even stronger in the Medicaid program.

The other thing I can tell you, though, is that I spend a lot of time talking to people in the health care marketplace, people in managed care and other places, and some of my colleagues in managed care tell me the greatest problem is not even in the increased drug expenditure, but in the increased costs in the rest of the health care system because of patients coming in, asking, "Hey, Doc, I saw this drug on TV; do I need it?"

Now, the docs say there are a certain number, maybe one-third, of their patients who come in who really need it, and that is good; it was a public service that was done. But they are saying there is another share of their patients who come in who did not really

need it, and they are eating up physician time in the managed care organization, increasing our health care costs and the costs of running an HMO or a managed care organization because of these physician visits, driven by drug company ads. And then the docs also say they have what are called the "worried well," people who think they need anything they might see on TV, and they will go in and ask for it. And there are doctors who get so tired of seeing them that when you sit down with them at the corner bar and talk it out with the doctors and ask them what they really do, they will admit: I prescribe the drug sometimes; if I do not think it will cause harm, I will go ahead and give it to them just to satisfy them and to help them feel like I have done something for them, whether they really need it or not.

Senator COLLINS. That has been my experience as well in talking to physicians in Maine, and obviously, a physician should not needlessly prescribe a drug, and I think we should all agree on that. It is very interesting that one study by Prevention Magazine found that an estimated 55 million people talked to their physicians last year about specific prescription drugs that they saw advertised. And as you point out, that can be a very positive thing; it can mean that that patient will get access to a drug that the patient needs. But it is somewhat disturbing and unsettling to me that the same study found that 84 percent of the time, the doctors did write the prescription. And indeed, when I have talked to physicians in Maine, in some cases, they have expressed the point that you have just made, and also the feeling that if they do not write the prescription, another doctor will.

So I think there are implications as far as overuse of pharmaceuticals or perhaps using a brand name product when a generic might do the job just as well.

Since my time is almost up, I want to give the other two witnesses a chance to comment on this issue also.

Dr. Rhodes?

Mr. RHODES. Yes, very quickly, I am an EU-registered pharmacist, and in England, we have been looking as we so often do at the American experience. Our feeling is that if the advertising were just informative rather than persuasive, it would be excellent; but of course, that distinction is artificial and, as has already been pointed out on my left, it clearly is persuasive.

Thank you.

Senator COLLINS. Dr. Danzon?

Ms. DANZON. I agree with you, Senator Collins, that it is a very difficult line to draw, because at this time, it is clear that consumers are becoming much more actively involved and want to play a role in their health care, and they want information. They are going to the internet, and they welcome some of the information they are getting from DTC advertising.

On the other hand, I think that when you have advertising for a service such as medical care, whether it is pharmaceuticals or physician services or hospital services, whether it is largely third-party payment, the likelihood that the consumer then goes in to ask for what was advertised is enhanced because they are not paying the full cost. So I think we should factor in when we are looking at the design of a health benefit that we have appropriate co-

payments and other incentives in there that prevent that overutilization.

Senator COLLINS. I see my time has expired.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank all of you for very helpful testimony. We will reserve the right to further question you via mail if we feel it is appropriate.

I want to thank you all. It has been very helpful.

We will now turn to our third panel, and I would like to welcome Mr. Ronald F. Pollack, executive director of Families USA, Washington, DC. This is a national organization for health care consumers which analyzes and reports on health care. From 1997 to 1998, Mr. Pollack was appointed the sole representative of a consumer organization to serve on the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Previously, he was dean of the Antioch University School of Law and the founding executive director of the Food Research and Action Center.

It is a pleasure to have you with us, Mr. Pollack, and we look forward to hearing your remarks.

Next, I would like to introduce Mr. Alan F. Holmer, president and chief executive officer of the Pharmaceutical Research and Manufacturers of America. His association represents the country's leading research-based pharmaceutical and biotechnology companies. Mr. Holmer was appointed by President Reagan in 1981 as deputy assistant to the President for intergovernmental affairs. In 1985, he became general counsel to the U.S. Trade Representative and was promoted to Deputy U.S. Trade Representative in 1987. In addition to his service on various councils and boards, Mr. Holmer has been an adjunct professor at Georgetown University Law School.

Mr. Holmer, thank you for being here.

Our final witness this morning will be Dr. Paul G. Abrams, chief executive officer of NeoRx Corporation in Seattle, WA, a biopharmaceutical company which develops innovative products to improve cancer therapy. He is also on the board of directors of the Biotechnology Industry Organization. Dr. Abrams has a broad background in both medicine and law as well as corporate management, basic science, and all phases of drug development, having held positions in Government and the private sector. He received his doctorate degrees in medicine and in law from Yale University, and he is inventor or co-inventor of 11 U.S. patents. On assuming his position with NeoRx in 1990, Dr. Abrams set about to transform the company from a diagnostic to a cancer therapy company.

Dr. Abrams, we welcome you and look forward to your testimony.

Mr. Pollack, why don't you start?

STATEMENTS OF RONALD F. POLLACK, EXECUTIVE DIRECTOR, FAMILIES USA, WASHINGTON, DC; ALAN F. HOLMER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON, DC; AND DR. PAUL G. ABRAMS, CHIEF EXECUTIVE OFFICER, NeoRx, SEATTLE, WA, ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION.

Mr. POLLACK. Thank you, Mr. Chairman, Senator Collins. Having listened to the previous two panels, one of the questions that came up over and over again is what is the relationship between doing something about moderating prices and expanding coverage. I would suggest to you that we really have a duality here of an approach that is absolutely necessary. We cannot merely solve this problem by focusing on moderation of prices. We cannot solve this problem by just dealing with coverage. Both of these things need to go hand-in-hand. Even if we moderate prices, there are going to be vast numbers of senior citizens who cannot afford prescription drugs that are prescribed for them today, and if we merely provide prescription drug coverage and do not do something with prices, that coverage is going to erode over time.

In the interest of time, what I would ask you to do is to look at the appendices attached to my testimony, and I am going to focus on five of the charts that are attached to that testimony. I will ask you to look at Appendix 6. Appendix 6 shows what we did in examining the prices of the 50 top-selling drugs for senior citizens and what has occurred with the prices of those drugs over the past 6 years.

Of the 50 top-selling drugs for seniors, 39 of them were on the market for the entire 6-year period. What you will see from that chart is that of the 39 that were on the market for the entire 6-year period, 37 of the 39 rose faster than inflation; three-quarters of them, or 30 out of the 39, rose at least one and a half times the rate of inflation; more than half, 22 of 39, rose at least twice the rate of inflation; one-quarter, 11 out of 39, rose at least three times the rate of inflation; and 6 of the 39 drugs rose faster than five times the rate of inflation.

If you look at the next chart, you will see what has happened with some of those drugs. For example, Lorazepam, which is used for anxiety, convulsions, Parkinson's, in that 6-year period rose in price by 409 percent. Furosemid, a diuretic, rose by 210 percent. Klor-Con 10, a potassium replacement, rose by 164 percent. Imdur, used for angina, rose by 122 percent. Lanoxin, which is used for congestive heart failure, rose by 90 percent.

And seniors, especially those who are uninsured, bore the entire brunt of this. For them, there is no such thing as discounts. For them, there is no such thing as rebates. For them, these prices are real, and this is one of the reasons why people are going across the border to get the drugs that they cannot afford in the United States.

If you look at the next chart, Appendix 8, we took a look at a widow who is living at 150 percent of poverty. We chose 150 percent of poverty, by the way, because many of the bills, Democrat and Republican, use that group as the group that is deserving to get extra attention in terms of subsidies. And you will see at 150

percent of poverty, a widow is subsisting only on \$12,525 a year of income. If you take two situations for this widow—if you look on the right-hand side, let us just assume she has gastrointestinal problems. She is likely to take Prilosec, and the annual cost of Prilosec alone for her is going to consume more than one out of nine dollars in her total income.

But take another very common situation. As Senator Frist indicated earlier, many seniors have a number of different conditions. If you take three conditions which are rather common—diabetes, hypertension, high cholesterol—and you look at the drugs for those three health problems—glucophage, Procardia XL, Lipitor—we are talking about a price just for those three drugs which can consume over 18 percent of that senior's entire income. Obviously, we have an affordability problem.

If I may, I would ask you to turn to Appendix 11, where you will see that, as other witnesses have done, we have examined what has occurred with some of the prices in the United States for the top 10 best-selling drugs and what are their costs in other countries—Canada, Great Britain, and Australia. And you will see—I will just mention a few of them—Prilosec, where the difference in price is two to two-and-a-half times as great in the United States; Prozac, two to two-and-three-quarters as great; Lipitor, 50 to 92 percent greater; and as you go down the line, you will see with the exception of Epogen, which is a unique story which I would be happy to go into during the question period, all of these prices are higher in the United States than they are in the other three countries. This squares with what the GAO has found in the United States and Canada in its reports in 1992 and 1994.

In closing, I would ask you to turn to Appendix. The last point I want to make is that I think we have seen a canard foisted upon the American public in terms of what moderation of prices would do to the industry. What the industry keeps saying is that research and development would be destroyed if we have moderation in prices—there is nothing further from the truth.

If you take a look at the various large drug companies and look at their annual statements—this is not something that was made up; it comes directly from their annual statements and from Fortune Magazine—compare the amounts of money that these companies are spending for research and development as opposed to what they are spending for marketing, advertising and administration on the one hand, and compare it to what they receive in profit.

Merck, for example, receives three times as much in profits as it spends in research and development. It spends two and a half times as much on marketing-related costs than it spends on research and development. Look at Pfizer. Pfizer's profits are higher than its research and development budget. Its marketing costs are more than double its research and development. Eli Lilly—profits are one-and-a-half times research and development; marketing costs are one-and-a-half times research and development.

Now, I am not suggesting by this analysis that we should have some arbitrary limitation on profits or that we should have some arbitrary limits on the market; but it is very clear that when the industry says the only thing that is going to slip when we do something in moderation of prices is research and development is clearly

fallacious. It is clearly exaggerated. We can have research and development at the same time that we moderate prices.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

[The prepared statement of Mr. Pollack may be found in additional material.]

The CHAIRMAN. Dr. Abrams?

Dr. ABRAMS. Thank you, Mr. Chairman.

I am representing more than 900 companies in the Biotechnology Industry Organization. Most of these companies are dedicated to improving therapies for diseases that most affect seniors—cancer, heart disease, Parkinson's disease, stroke, osteoporosis, Alzheimer's disease, just to name a few.

Fewer than 5 percent of our companies have a product on the market; even fewer make profits. They represent hope for improved future therapies that will, when successful, improve patient well-being and reduce the overall costs of care substantially.

I am here, therefore, to speak for the future patients and future treatments that do not have another constituency. We in Biotech believe very strongly that seniors need affordable and expanded access to medications and that that problem needs to be addressed. Make no mistake about that.

Three and a half decades ago, a halfback for the Chicago Bears, Brian Piccolo, developed testicular cancer. He was treated with chemotherapy, and he died. His life story was made into a movie called "Brian's Song," which you may have seen. Three and a half years ago, Lance Armstrong developed testicular cancer and was treated with chemotherapy. Last year, he won the Tour de France.

The difference between these outcomes was the development of a single drug—Cisplatin—discovered in an academic laboratory in the United States and brought to market by a pharmaceutical company.

Several weeks ago at the annual cancer meetings, my company, NeoRx Corporation, announced that 18 of the first 40 patients it had treated on its protocol for a disease called multiple myeloma had achieved complete remissions. Trials of this agent in prostate cancer and breast cancer will begin shortly. Additional cancer therapies are expected to begin human clinical trials in the next 6 to 12 months. We have a total of 65 people in our company.

No orator can match the poignant eloquence of patients' dramatic relief from their excruciating pain, their new leases on life, and what that means to them and their families and to their communities. One drug can make a big difference—it did for Lance Armstrong and thousands of others like him. If our drug continues to show the same results as we have seen to date, it will, too.

Breakthrough drugs provide real benefits to real patients every day, but they do not arise in a vacuum, and they could not have been accomplished without huge investments—and you know that we are talking about hundreds of millions of dollars just to bring one of them to market. For companies such as ours, without product revenues, this cash can only come from investments.

We believe, therefore, that it is vitally important to solve the problems of seniors' access without the chilling effect on invest-

ments that price controls, direct or indirect, or even the threat of price controls, as occurred in 1993 and 1994, did to the industry.

Biotechnology is a very fragile industry. Just weeks ago, a joint statement by President Clinton and Prime Minister Blair which was misinterpreted clipped \$35 billion from the valuations of biotechnology companies on the market. Only a later clarification partially reversed that slide.

So our suggested solution focuses on this issue of coverage—not controlling prices. It provides for a subsidized access to insurance for a drug benefit and for a stop-loss provision to limit the total outlay for drugs in a given year.

These suggestions, I would submit, are preferable to current proposals that substitute Canadian price control boards to regulate prices or open reimportation, or establish a single U.S. purchaser that will have the power to set prices.

Any of these—any of these—would chill investments in biotechnology drug development. Our solution and our proposal would not. Once the specter of controls becomes real, investment will dry up. This is not hysteria. This is not hyperbole. It happened before. It will happen again, because economic forces inexorably drive investments to their highest return. That is why the U.S. is winning out over the more controlled, regulated, and lower-return economies of Japan and Europe.

Canadian price controls would at best provide a discount to current prices and raise difficult enforcement and definitional questions of whether two drugs were the same. Focusing on coverage would reduce out-of-pocket expenses to copay and not involve the Canadian Government.

We urge you to pass a plan that provides real benefits to seniors while preserving the investment climate for new drugs that today's seniors and tomorrow's seniors can enjoy.

Thank you very much, Mr. Chairman and members. I look forward to answering your questions.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Abrams may be found in additional material.]

The CHAIRMAN. Mr. Holmer?

Mr. HOLMER. Mr. Chairman, thank you for the opportunity to be here today; and Senator Collins, thank you for sticking around to hear the third panel.

First, I will note that I disagree with almost all the numbers that Mr. Pollack has presented, and I do disagree with all of his conclusions. We can talk about that in the question-and-answer period, and I would hope, Senator Collins, that we might talk about direct-to-consumer advertising as well; I know that is a particular area of interest that you have expressed this morning, and I would like to have a chance to talk about that further.

The pharmaceutical companies that I represent are concerned any time any senior is unable to obtain access to our medicines. That is why we strongly support expanding drug coverage for seniors, but doing it through private insurance plans and not through a new, one-size-fits-all, big government solution—legislation along the lines of that that Senator Frist and Senator Breaux have introduced, for example.

Private insurance coverage would help in two ways. First, coverage helps to pay the bills for medicines; but second, coverage also provides access to price discounts freely negotiated in the private sector. Senator Frist raised with Panel 2 that question: How big would the discounts be? According to the Lewin Group, discounts freely negotiated with pharmacies and with manufacturers would total somewhere between 30 and 39 percent.

Interestingly, when we heard Senator Johnson describe the price disparities between the U.S. and Canada—and I do not know if his numbers are right or not—but he had Canadian prices that were about 65 percent of the U.S. prices. That is almost the exact difference that would be achieved through negotiated discounts to the private sector.

So Mr. Chairman and Senator Collins, that is what we are for—private sector insurance coverage.

Here is what we are not for. We oppose a variety of price control proposals, because if there is anything that history has taught us, it is that price controls do not work. When Ways and Means Committee Chairman Wilbur Mills spoke on the House floor in 1965 when Medicare was established, he said, quote: "There is no intention to tell doctors what they may charge their patients." But now, Medicare relies on a complex maze of price controls on doctors and other health care providers. Price controls would have a serious negative impact on our research. We urge you to oppose price controls in any form.

We also oppose import proposals that would repeal a landmark consumer protection law, the Prescription Drug Marketing Act of 1988. My testimony includes a range of concerns that we have, but the largest of these concerns is our strong belief that these proposals would put the safety of patients at risk. We share the views of FDA Commissioner Dr. Jane Henney, who said that she feared that if this consumer protection law were repealed, Canada would "somehow be used as a front for counterfeit or contaminated products becoming available."

These safety concerns are also shared by Dr. Henney's immediate predecessor, Dr. David Kessler.

So before you rush to repeal the 1988 Act, I encourage you to remember that the exploding growth of internet pharmacy sales is overwhelming drug safety regulators and law enforcement agencies. According to the U.S. Customs Service, the number of pharmaceuticals seized entering the U.S. increased by 450 percent between 1998 and 1999.

At a hearing at the House last week, the FDA disclosed that the agency has inspected only one in four foreign drug manufacturers who shipped to the U.S. The World Health Organization estimates that about 5 to 8 percent of drug products shipped to the U.S. are counterfeit, and some have estimated that 50 to 70 percent of the drugs in some developing countries are counterfeit.

I would also note the story on the front page of today's Washington Post, in which the WHO concludes that "The world could be plunged back into a pre-antibiotic era," and among the concerns that were cited by the WHO is the fact that there are counterfeit drugs frequently used and available in the developing countries.

Mr. Chairman and Senator Collins, I think the Customs Service does a pretty good job, but their task is daunting. And to help you understand the challenge, I asked one of our member companies to send me an original pack of their product plus a counterfeit. What I have here—and I would like to share it with you, Mr. Chairman, and with Senator Collins if my staff could just bring those up to the chairman—are two separate packs, four Viagra pills each, one a legitimate product made in Australia, the other a counterfeit made in Malaysia. I am not submitting these for the record, because the company made me promise that I would send it back to them, but I encourage you to look at those closely and see if you can tell which is which. I know I could not when I looked at them.

This example underscores the challenge the Customs Service faces and the extent to which patients' lives could be put at risk if that 1988 consumer protection law were repealed.

So to come full circle, Mr. Chairman and Senator Collins, we want to work with you to be able to address this problem and to address the issue that you have raised, that in some instances, seniors are not able to afford their medicines. But the correct way to do that is through prescription drug coverage through expanded private sector insurance.

With that, I will conclude, Mr. Chairman. Thanks for the opportunity to be here.

[The prepared statement of Mr. Holmer may be found in additional material.]

The CHAIRMAN. Thank you.

This has been very helpful testimony, and it is very daunting to seek a solution to the problem, but there is no question in my mind that we have to find a way to take care of what we are experiencing.

The solution is not obvious, but certainly, we have to try to find some way to provide equity for the people of this country. And the fact that other countries can utilize the price controls and other aspects and then to say that we ourselves should not take advantage of them but instead must go across the border to purchase medicines is not a very satisfactory answer.

Mr. Pollack, the pharmaceutical industry argues that increased price competition through reimportation will chill research and development spending. Are you worried that if Congress uses such a measure to address increased drug costs, we will look back in 10 or 15 years and wish we had not taken the current research and development spending for granted?

Mr. POLLACK. Well, Mr. Chairman, I think there are a number of answers to how we might moderate prices. When we find a regimen that we settle on that is successful, and it does moderate those prices, I do not think it is going to have a significant impact at all on research and development. Will it have no impact? I am not sure I would say that; but I think the impact is wildly exaggerated. As my testimony indicated, the portion of discretionary resources available to the pharmaceutical industry is far in excess of the amount of money they spend on research and development, and to say that the one and only place that would be impacted by a moderation of prices—and research is research and development—is clearly a gross exaggeration.

So I do not think that we are going to see any significant diminution in research and development. In fact, it is in the interest of the pharmaceutical industry, not just the American public, that they undertake research and development. This is not done just out of altruism. Research and development is part of the process of bringing new products to market and increasing profit. I do not think we are going to see a significant diminution in R and D.

The CHAIRMAN. Mr. Holmer?

Mr. HOLMER. If the importation proposal were to be enacted, or if price controls were to be enacted, would there still be a pharmaceutical industry? Yes, I think there would be. I am not sure there would be a biotech industry, and Dr. Abrams might want to speak to that; but there would be a pharmaceutical industry. But the impact on the industry and on research and on the patients who are waiting for those cures and treatments I believe could be quite profound, and the industry could be profoundly different, and the benefit for patients could be as well.

As you know, my children, my son who is 20 and my daughter who is 17, are both waiting for the cure for cystic fibrosis. Their life-expectancy is 33. The impact that price controls could have on both biotechnology and pharmaceutical research could be, I believe, quite profound.

There will still be a pharmaceutical industry, as Mr. Pollack indicates, and R and D will still go on. But it certainly would not be at the level that it is now, and there would be a significant negative impact, as we saw in 1994 and 1995 with the impact of the Clinton price control proposals.

The CHAIRMAN. Dr. Abrams?

Dr. ABRAMS. As I said in my opening remarks, even the specter of price controls chills investment in our industry. We do not have profits, so we are not subject to the analysis that Mr. Pollack tried to give you a moment ago. Moreover, I think there were several red herrings there, that is, no one is saying that all of the decrease in expenditures would come out of R and D. But it is very clear that if you are making a bet—because remember, at the stage of phase one trials, only 18 percent of products make it, and part of the expense is the huge expense for all of the failures.

So if you were at the stage of R and D, and you are making a bet whether it is a pharmaceutical company that has profits or whether it is us spending our capital, we have to decide where that money should be spent. We would like to take some big bets. Those big bets, if they are successful, will turn into major improvements in therapies and outcomes for patients. If we are put in a situation where the cost of capital becomes very high because the returns are perceived—just perceived—to be compromise, then the bets that you can take are not going to be as large, and the opportunities for developing some real breakthrough medications will go down. They will not disappear, but they will go down.

Mr. POLLACK. Mr. Chairman, if I may just add one word, the pharmaceutical industry has been advertising rather heavily, as you know, and they have an advertisement in today's Washington Post that essentially repeats what Mr. Holmer just said a moment ago, namely, that he presumes that if the bill offered by Senators

Frist and Breaux were enacted, we would see discounts of 30 to 39 percent, and he extols the virtue of it.

Clearly, the industry is in effect admitting that there is a very significant cushion and that if we did achieve those discounts, the industry would not be harmed at all. Now, I question the assumption that Mr. Holmer has that a private sector, drug-only bill is going to achieve that 30 to 39 percent discount, but I am very pleased to see that the industry is saying that they can live with 30 to 39 percent discounts that reduce the prices that seniors bear today, and it will not harm the industry. It was a very wonderful admission that we received today.

The CHAIRMAN. Mr. Holmer, would you like to respond?

Mr. HOLMER. I am pleased that Mr. Pollack appreciates our advertising; we stand behind it, and it underscores the commitment that this industry has to achieve expanded drug coverage for seniors but to be able to do it in the right way, where quality and cost controls are done in the context of private sector competition.

I would also assume, as I think Dr. Schondelmeyer referred to earlier, that it is quite likely that in the context of Medicare reform, there will be an expansion of the prescription medicines that are available to our senior citizens. So it is not quite as stark as Mr. Pollack would like to have you believe and not as stark as Dr. Schondelmeyer would like you to believe as well.

But we stand behind our commitment, Mr. Chairman, to work with you and every member of the Senate and every member of the House and with the President to try to get this issue addressed at the earliest possible time, but to do it not with big government, one-size-fits-all solutions, but truly through the private sector.

The CHAIRMAN. You talk about competition being the rescuer here. When you have the protection of the law against competition, how can competition be the answer?

Mr. HOLMER. I am not sure I follow your question.

The CHAIRMAN. In other words, you have patents. So to say that, somehow, competition is going to reduce these prices when there is no competition, at least for a number of years, how is that going to work?

Mr. HOLMER. Well, you could repeal the patent law if you wanted, but you would not have many drug discoveries. Clearly, intellectual property protection is the lifeblood of the pharmaceutical industry and the biotechnology industry, and without that kind of patent protection, you would not have the incentives for the companies necessary to be able to achieve that.

I would also note that for our industry, the average period of market exclusivity is in the range of 11 to 12 years, whereas for all other industries, it is about 18-1/2 years that they have in terms of their market exclusivity.

Dr. ABRAMS. Mr. Chairman, if I could comment on that as well, there are many different approaches to most diseases, and even within a drug class, there are many different drugs that do more or less the same thing; so that while you may have patent protection that covers a particular formulation, that does not stop other companies from coming out either with totally different approaches to that disease or with similar approaches using different drugs; and there are countless, countless examples of that. That is where

the competition comes. The reason you do not want to repeal the patent law is that you need to be able to protect your particular formulation because you hope it has particular advantages.

I just want to underscore one other point so it does not get lost, which is that for our part of the industry, for the biotechnology industry, whatever the prices turn out to be, as long as they are achieved without external imposition of price controls, the investment community and the ability of companies to invest in those developments will continue. As long as the specter of some kind of external control comes in, the risk profile that is associated with developing drugs is so high that a lot of the capital will dry up, and that is the point that I would like to emphasize to you.

The CHAIRMAN. All this bill does is put competition into the scenario here. All we are saying is that it is a weird world, you might say, as to how different countries handle pricing. But you are asking us to stand aside and watch people on the other side of the border enjoy much lower prices, and you are still selling. So we are going to introduce a little competition into the field. What is wrong with that?

Dr. ABRAMS. But it is not real competition.

The CHAIRMAN. Mr. Pollack?

Mr. POLLACK. Mr. chairman, you pointed out something that I think is very appropriate. I do not favor eliminating patent laws, but when we in effect have Government policy that establishes a monopoly over an essential need, we normally do something in the process to moderate prices.

I was very happy to hear Mr. Holmer speak favorably comparing his bill with what is done in Canada. In Canada, the provinces negotiate with the drug companies for the prices, and they are able as a result to generate lower prices for those drugs.

Obviously, if we establish a drug benefit in the Medicare program, we will have that same kind of leveraging power for America's consumers, and we will get prices down.

The CHAIRMAN. Mr. Holmer?

Mr. HOLMER. If I could follow up, Mr. Chairman, when you talk about competition, it is important to remember that over the course of the next 5 years, it is anticipated that there will be \$50 billion in pharmaceutical sales that will go off-patent during that time period. So there is a significant amount of competition that is going to be generated into the system quite automatically under the current system.

Dr. ABRAMS. I would like to also comment on Mr. Pollack's assertions. No. 1, as far as biotech products are concerned, about one-third of biotech products are not even sold in Canada, so one of the things that the provincial negotiation process does is reduce the number of available drugs. And that is a very important point to make as we all sit here and think in our minds that we know how a drug works, and we know everything that that drug will actually do and what the best way of using it is. That is not the case.

What happens is that a drug gets into the marketplace, just like a surgical procedure gets into the marketplace—I am sorry that Senator Frist is not here, because he could speak to you eloquently about cardiac bypass surgery which has evolved over time—what happens is that data is collected over time; the use of the drug,

positively or negatively, evolves. And when you ossify a system so that you have people who really do not know what the drug does, which is the regulators, making decisions and negotiating prices and negotiating access, what you do is you enfeeble the vigor of the ongoing research and development process that happens after a drug is approved as well, and you wind up denying the entire population the benefits of knowing some of the drug's negative effects if the drug should not be used, or some of the enhanced positive effects that a drug has.

So if you take a snapshot in time, yes, you can say that in a given snapshot in time, it makes sense to do A or B; but what we really have is a process by which drugs and procedures get introduced into the system in a highly-regulated environment, and then they evolve over time to either combination uses, reduced uses, enhanced uses, that we would never discover if we had somebody sitting there as a gatekeeper to begin with, saying, yes, we will pay for this, and no, we will not pay for this, or this will get on the formulary, and that will not get on the formulary.

I do not think that the Congress really wants to import the Canadian system into the United States, and I think that is what Mr. Pollack's comments were really directed at.

The CHAIRMAN. Mr. Holmer, you indicated that many other countries employ price controls on pharmaceutical products. Is it your position that if other countries relaxed or removed their price control regulation, the pharmaceutical companies would voluntarily reduce the prices they charge Americans?

Mr. HOLMER. As you could appreciate, if I were to tell you about what it is that the pharmaceutical companies are likely to be doing in the future with respect to their pricing activity, there are probably some folks at the Justice Department who would like to have a chance to come and talk to me about antitrust issues.

We do not talk with our companies about their past, their current, or their future pricing activities, so I am really not able to get into that this morning.

The CHAIRMAN. Mr. Pollack, we heard testimony earlier that price regulation leads to decreased competition and in fact less incentive for generic drugs to come to market. Are you worried that generic drug companies will market fewer generic drugs if we allow free trade through reimportation?

Mr. POLLACK. No. I do not see why there is any reason that there would be any reduction in the availability of any of these drugs, whether they are generics or brand name drugs.

When we talk about the reimportation of drugs, clearly, we know that that is not going to be "the solution" to prices. It is a symbolic response, because obviously, we do not have as many people in Canada as we have senior citizens in the United States. But it does show the seriousness with which Members of Congress are treating this issue.

I think there are ways in which we can get these prices under control. I think we can do it in ways that provide bargaining power for those people who bargain on behalf of the ultimate consumers of drugs, and I think probably the best way we will be able to accomplish that will be by establishing a benefit in the Medicare program so that we can get the kinds of discounts that people in Can-

ada have been receiving, which is now the envy of the United States.

So I am not sure that the reimportation is going to be "the answer." I am very appreciative of proposals that have offered reimportation, because I think it underscores the need for greater equity between countries and moderation of prices; but ultimately, if we are going to solve this problem, I think we are going to need a much more comprehensive solution which is going to involve and include putting prescription drug coverage in the Medicare program and using that purchasing power to keep these prices down.

The CHAIRMAN. Is it realistic to think that at the same time we did it for Medicare, we could do it for Medicaid and we could do it for the public generally?

Mr. POLLACK. We are already trying to do it in the Medicaid program, of course. We have legislation to that effect. And thankfully, with the admission from the industry, we know that there is a cushion that the industry could well live with, and I think that if we provided that kind of set of discounts for all seniors, that would be extraordinarily helpful.

So my view, Mr. Chairman, is that the best way that we can deal with this problem is not through piecemeal solutions; it has got to be somewhat more comprehensive, and it has got to include providing a broader purchasing power that would include Medicaid, it would include Medicare, so that those people who need drugs the most get the same benefit of discounts that other large purchasers today receive.

The CHAIRMAN. Mr. Holmer, you indicated that insurance coverage is the right pricing solution. I agree that we need to increase health insurance coverage for all Americans, and I have several proposals to do just that. But many of your critics say that increasing drug costs is the biggest reason for huge insurance premium increases, making health insurance unaffordable. Doesn't this mean we need to work on both problems?

Mr. HOLMER. With respect to premium increases, I would note in particular that if you look at health insurance premium increases that occurred in 1998, more than 70 percent of premium increases were due to factors other than pharmaceutical products, with prescription drugs representing only 28 percent of that increase.

Clearly, from our perspective, you can only do so much at one time period. We think that clearly, the focus in the Congress has been to focus on prescription drug coverage for seniors, and we are committed to being able to do that.

I share the view of Mr. Pollack that it is very important that that be done on a comprehensive basis, and we would like best for that to be done in the context of overall comprehensive modernization of the Medicare program, and we hope that you and your colleagues will take that under advisement. In the event that you are not able to do that this year, we would also support being able to do this on a comprehensive basis but through private insurance mechanisms.

We would passionately oppose just taking the current Medicare program which the Health Care Financing Administration is not able to adequately administer presently and just adding on a brand new drug benefit to that. We think that experience and history

teach us that if you do that, you will ultimately have price controls in the pharmaceutical industry, and senior citizens will have limitations on access to medicines. We believe that that would be bad for patients, both those who need medicines that have already been invented and also for those patients who are waiting for those new cures and treatments.

The CHAIRMAN. Mr. Pollack?

Mr. POLLACK. I would just respond by saying that the proposal that the industry is offering I think is really a mirage. What they are offering is private sector, drug-only policies. As we have already heard from the insurance industry, they are not going to offer these policies. They have been very clear about that. And to the extent that we prevailed upon the insurance companies to offer these policies, I suggest that what we are going to see is incredible adverse selection.

It is the same kind of adverse selection that has led to Medigap premiums being sky-high. If you look at the top-of-the-line Medigap policies and compare the two policies, one that has prescription drug coverage and the one that does not, you will see that the difference in the premium is over \$1,700 a year.

I suggest to you that a private sector insurance policy that is drug-only is going to actually result in more adverse selection than we have experienced in the Medigap program.

What that means is that, first, we are not likely to see the insurance industry offer it, and to the extent they do offer it, the prices are going to be sky-high, and they are going to be unaffordable. And that same policy that Mr. Holmer extols, which would only provide some relief for people below 150 percent of poverty, would leave those individuals with incomes above \$12,525 with no subsidy at all. Clearly, that drug policy would be unaffordable for the vast majority of seniors.

That is why I say it is a mirage—it looks good from a distance, but when you start examining it more closely, you will see that it will not provide significant relief for the senior citizens who need prescription drug coverage.

The CHAIRMAN. Mr. Holmer?

Mr. HOLMER. If I could just provide a very brief response, in response to the concerns that have been raised by some that Mr. Pollack alluded to, we went to the experts. We asked actuarial and economic firms, including Milliman and Robertson, Towers Perrin, and Abt Associates, is it possible to be able to offer this private sector, drug-only plan. And these actuaries and economists note that a private prescription drug insurance program can work if designed properly. They also note that adverse selection is one of the most difficult issues, but that there are various tools that can be addressed.

If possible, Mr. Chairman, I would like to be able to submit those three actuarial reports for the record of this hearing.

The CHAIRMAN. Without objection.

[Documents may be found in additional material.]

Mr. POLLACK. And I guess I would ask Mr. Holmer at the same time to name three companies in this country that are prepared to offer these policies. Name one.

Mr. HOLMER. I am quite confident based on this kind of analysis that they will step forward. I know there is testimony being taken in the Ways and Means Committee this morning where I understand the American Association of Health Plans is going to be speaking quite enthusiastically about the kind of plan that I have just described.

The CHAIRMAN. Mr. Abrams, you mentioned that European and Japanese governments are trying to undo counterproductive policies and attitudes that have hindered the development of your industry. Can you be more specific about what is happening in these countries, and do you think that research-based companies like yours will leave the United States in favor of these countries?

Dr. ABRAMS. I do not think we will leave the U.S., but what I tried to say in my written testimony was that both Europe and Japan are trying to emulate the academic, small company/large company financial market system that has evolved in the United States so that companies, usually smaller companies, can take advantage of some academic research and take it to the next stage of development, and then, depending on the size of the market, either develop the product themselves or do a partnership with a larger pharmaceutical company wherein that product can get to market.

The reason why all of this takes place is that through the evolution of the system that has occurred, some of it due to acts passed by Congress such as Dole-Bayh several years ago, which enabled academic people to control their patents rather than the Government, we have a unique system. I am going to a pharmaceutical meeting in Europe next week, and they are trying very hard to get their systems, which have been much more highly regulated, much less conducive to entrepreneurship, to move toward that particular system, and there are lots of generational and perception problems that they have because a lot of their practices, academic practices, government support of academic, foundation support of academia, the public markets, the appetite for risk, etc, are just not ingrained attitudes.

But you go to these conferences, and you will hear the Europeans step up and say "Here is what we are trying to do." And over the course of the last few years, they have made some progress, and there are a lot more biopharmaceutical companies right now in Europe than there were several years ago, before they unleashed some of this entrepreneurial activity.

I was in Japan a year and a half ago, and their goal—their goal—is to have 1,000 Japanese biotech companies within the next 5 to 10 years, and they know that in order to do that, they have to unravel an awful lot of their financial and market regulatory scheme in order to induce capital to flow into those particular areas.

So we are the envy of the other major markets in the world, and I would just once again urge you and your colleagues to tread very, very cautiously in trying to fix one end of the system without aligning the interests of the other end of the system, because—you asked a question earlier about whether we would regret having done something like this 10 years from now—the problem is that you can really never prove what you would have had if you had

done something differently. That is a very difficult thing to do, and that is why those opportunities really do not have much of a constituency.

But in fact we have demonstrated through the development of our mixed system in the United States that the process works, that capital flows into these areas, that drugs like ours, which I can tell you was actually given up by a major chemical company and given to us because they were not sure that it would work, and they did not think that it would establish an appropriate market for their particular interests, if the success continues, we are going to have a major advance in cancer therapy which was developed not just because of us but because of the system that is in place to enable these tradeoffs to occur.

That is what I was trying to refer to in my testimony, and I believe very strongly that both Europe and Japan will be trying to emulate us the way they are now, although they will have difficulties doing it.

The CHAIRMAN. Thank you.

Mr. Pollack, do you have any last words?

Mr. POLLACK. No. I thank you, Mr. Chairman, for conducting this hearing. I also want to applaud your leadership in getting this issue front and center.

Obviously, this is a complex issue, and my hope is that over the course of the next year or two, we will focus on both things—getting coverage for seniors and moderation of prices. I think we can do both. I think we can do it with a thriving industry, and I look forward to working with you on that.

The CHAIRMAN. As you know, I sit on both committees, so I can assure you that I agree with you, and I am going to do everything I can to make sure we work on both ends of the problem.

Mr. Holmer, any parting words?

Mr. HOLMER. Nothing further. Thank you, Mr. Chairman.

The CHAIRMAN. I thank all three of you for very helpful testimony. We face a daunting problem which is crying out for a solution, and I am dedicated to finding one.

Thank you.

[Additional material follows:]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR JOHNSON

Mr. Chairman, Senator Kennedy, and Members of the Health, Education, Labor, and Pensions Committee, I thank you for allowing me to submit my statement in relation to today's hearing on prescription drug safety and pricing.

The discussion of prescription drug accessibility, affordability, and safety has been elevated to new heights in the last year as we in Congress work to develop an efficacious and cost-effective approach to providing some sort of relief for consumers throughout the United States.

On June 9 of last year, I joined my colleague from North Dakota, Senator Dorgan, by sponsoring the "International Prescription Drug Parity Act of 1999" (S. 1191) and applaud the Senator for all of his work on this issue. Additional sponsors of the bill include three of our colleagues, Senators Wellstone, Levin, and Snowe. Congressman Marion Berry, along with Congressman Bernard Sanders who will be testifying today as well, introduced companion legislation in the House, H.R. 1885, which currently has 84 cosponsors.

The "International Prescription Drug Parity Act" would allow American wholesalers, distributors, and pharmacists to re-import prescription drugs made in the U.S.A. that were shipped to foreign distributors. It also provides for a labeling and record keeping system to ensure that all reimported drugs meet U.S. safety standards. It has been cited by many pro-consumer groups as a positive step towards leveling the playing field for prescription drug prices and would save U.S. consumers billions of dollars by allowing the safe reimportation of American-made, FDA-approved prescription drugs.

Senator Gorton has also introduced an approach towards correcting the price disparities that exist between the U.S. and other countries by amending the Robinson-Patman Anti-Discrimination Act, thus requiring drug manufacturers be required to sell their products in the United States at the same price they are sold in foreign countries. We are all working to address the concerns of not only our constituents in our respective home states but for citizens across this nation that rely on prescription drugs for their health care needs. I believe that every member of Congress and panelist here today is deeply concerned about the rising out-of-pocket costs for prescription drugs and hopefully we can address many of these concerns here today before this Committee.

Along the lines of that debate, I have sponsored two additional bills aimed at lowering prescription drug prices, one with my colleague Senator Kennedy called the "Prescription Drug Fairness For Seniors Act" (S. 731), and the other called the "Generic Pharmaceutical Access and Choice For Consumers Act" (S. 2501). S. 731 works to end the unfair price discrimination that exists against seniors and those disabled on Medicare without drug coverage in this country. My other bill, S. 2501, increases consumers' access and choice of quality, FDA approved generic prescription drugs. Generic drugs provide a safe, effective and affordable alternative to more expensive brand drugs for millions of Americans. Therefore, I would encourage the Committee as it considers drug prices to not only oppose efforts to prevent Americans access to generic prescription drugs, but to work toward increasing consumers ability to choose and use generic prescriptions. The Committee should take a firm position against extending patents, either directly or through a biased process for authorizing patent extensions. Legislation that bypasses the orderly, conventional authorizing committee and floor process, is an unlikely way to develop legislation that provides for an unbiased patent extension process and one that could end up costing the American taxpayers billions of dollars in extra drug costs.

CONCERNS SURROUNDING THE ISSUE OF PRESCRIPTION DRUG REIMPORTATION

Perhaps the number one concern mentioned in regard to the reimportation of prescription pharmaceutical is the safety of the consumer. As with any product that passes through multiple distribution channels, it is important that a baseline be established to ensure proper handling and storage. This is particularly crucial in maintaining the therapeutic equivalence of prescription drugs.

The legislation that I am cosponsoring with Senator Dorgan addresses this concern by implementing assurances that any prescription drug reimported under this proposal be manufactured, packaged, and labelled according to FDA standards. Manufacturers would be required to provide documentation demonstrating FDA compliance to a qualified purchaser who can then reimport the pharmaceutical back into the United States.

This safety net addresses many concerns that arise when pharmaceutical are re-packaged and resealed to be sold in greater or lesser quantities to customers. Orig-

nal packaging and labelling requirements allow the purchaser to inspect the product for defects or damage and ensure a degree of confidence in the consumer that this product is the same as that manufactured and distributed within the United States.

PERSONAL STORIES FROM SOUTH DAKOTA

Presently, anecdotal evidence suggests that thousands of Americans cross the border to see Canadian doctor who, *quid pro quo*, are willing to accept payment in cash to write prescriptions. They then fill their prescriptions for 25-50% less in cost for many popular prescription drugs. Here are several stories that have been shared with me over the last year:

From a primary care physician in Watertown, SD,

"I am sure you may have heard many horror stories regarding the cost of medications to our individuals. Most of the people here in the rural communities do not have prescription coverage and this is a very significant burden. Sometimes they will cut back some of their medicines and these may be important cardiac medications because they can't make it to the end of the month. Or, they will cut back on some basic nutritional needs regarding their groceries. It is certainly sad when people can go down to Mexico or up to Canada and get their medications for about one fourth of the cost . . . it's the classic old question of guns or butter. I support the international prescription drug bill 100 percent."

From a pharmacist in Mitchell, SD,

"We have battled this issue (pricing disparities) for years. Thanks for picking up the ball to help our patients."

From a 72 year-old woman in Arlington, SD who spends \$242.99 a month on prescription drugs,

"The meds are so high in South Dakota. I try to get as much of them in Mexico as I can. I don't understand why there has to be such a difference in price."

From an 80 year-old man in Dupree, SD who spends \$200.00 a month on prescription drugs,

"I had one prescription that cost \$375 per month. It's robbery without a gun!"

Some seniors even go so far as to "bend" the law to meet their prescription drug needs. A 49-year old man from South Dakota who spends \$125.00 per month on prescription drugs,

"We go to Mexico once a year and smuggle back what we can."

And finally, a 41-year-old man suffering from a disease that requires daily medication at a cost of more than \$400 per month,

"I want you to know that while I recognize that seniors are particularly hurt by unfair prescription pricing due to their fixed incomes, other Americans also feel the pinch. The same medication that I take is available in Mexico at less than half the price that it costs me in the U.S. Unfortunately, I can not afford to travel to Mexico periodically to obtain my prescription."

PHARMACEUTICAL INDUSTRY ALLEGATIONS

Numerous studies have been conducted that highlight the price differentials that exist between the United States, our neighbors to the North and South, and countries in the European Union. Several reports suggest that pharmaceutical prices are substantially higher in the United States than other countries.

The pharmaceutical industry presents many economic and proprietary rationales for price disparities. From price controls to R&D to currency exchange rates, arguments are made that the prices garnered by some pharmaceutical companies are justified in a world where price is a measure of willingness to pay and price elasticity, not compassion or empathy.

Industry representatives have stated it would be profoundly pernicious to allow for the reimportation of pharmaceutical from other countries who purchase them at a much lower cost than our nation's senior population as this will create instability in the world's pharmaceutical markets. Personally, I can think of nothing more pernicious than charging seniors prices for prescription medications that cost far more than the majority of seniors are able to pay without sacrificing one or more basic needs in their lives.

In my home state of South Dakota, I am conducting prescription drug meetings where constituents are able to communicate their concerns regarding prescription drug prices and express their ability, or perhaps inability, to pay for therapeutic regimens prescribed by their physician. Many of them ask, "Why are citizens of other countries able to purchase their prescriptions at such lower prices?" After all the arguments I have heard from the industry on why this is the case, I have yet to hear an acceptable response that I could give.

Perhaps the most disturbing argument that I have heard in the past year came from an industry representative during an Alliance for Health Reform briefing last year. Our colleague, Senator Rockefeller, read a question from the crowd that asked why this individual's brother-in-law got the same medication from the same U.S. manufacturer for a considerable amount less. What I heard in response was shocking. The following quote is taken verbatim from the transcript of that briefing:

"Price discrimination is an economic concept that merely means different people in different markets are charged different things. In this particular case, price discrimination exists between the Canadian market and American market, for lots of reasons: differences in medical practice, how much of the product is sold, difference in exchange rates, different kinds of patent protections, the length and cost in time of distributing drugs and the marketing of drugs, and differences in living standards.

[You] could have used Mexico as your example and would have found that it is less than a third of the price potentially and that's in large part because the standard of living is substantially lower and they can afford so much less. Beyond that, and the other income differences, there is the difference in willingness to pay."

I would like to say a couple things about this quote. First, price discrimination does exist in markets so long as information is not shared between parties. In the age of the Internet, seniors are increasingly aware of how some pharmaceutical manufacturers have been discriminating against them and placing the burden of profit margins squarely on the backs of seniors. With a click of the mouse, seniors can compare the prices they pay and those of our neighbors to the North and South. Second, the idea that our nation's seniors are charged what they are because they are willing to pay is perhaps the most insensitive of all arguments. Can you imagine measuring the value of someone's life by whether or not they are willing to fill their prescription to control their cholesterol level or pay their rent? Thirdly, the standard of living that exists for most seniors in the United States is precisely the reason why we are having this hearing today. The simple fact is many seniors are not able to meet all of their basic needs and adhere to their prescription regimen. The number of South Dakotans who, due to their standard of living, can not afford their prescription drugs suggests that the pricing of pharmaceutical goes far beyond reasons based on standard of living and willingness to pay otherwise South Dakotans would have no problem affording their prescription drugs.

CONCLUSION

Mr. Chairman, I am reminded of a popular fast food chain motto some years back that proclaimed, "Make a run for the border." Who would have ever thought that we would be applying this same motto to the citizens of our country with regard to their prescription drug needs.

The legislative approaches taken by myself and my colleagues here, Senator Gorton, Senator Dorgan, and Representative Sanders, are all appropriate responses to the discriminatory pricing practices engaged in by much of the pharmaceutical industry. For years, our nation's seniors have paid the price in more ways than just at the pharmacy counter for the cost of their prescription drugs. Improper prescription drug usage results in thousands of deaths a year though the exact number of seniors included in this number may never be known. How many seniors skip a day's pill or cut them in half in order to stretch their prescription just one more day? I would argue that even one is too many.

Mr. Chairman, I know that this issue if of great personal interest to you as you have recently introduced, S. 2520, the "Medicine Equity and Drug Safety Act of 2000." Your work on this legislation, along with Senators Wellstone and Collins, has helped give this issue the visibility it needs to become a part of the general discussion on prescription drug costs. The fact that Vermont, Minnesota and Maine share a border with Canada lends even greater importance to this issue with your constituents. South Dakota, though it does not share a border with another country, has an increasing number of individuals willing to make the drive to either Mexico or Canada, knowing full well that the savings are great enough to more than offset any expenses occurred in the process.

While Congress debates the prospect of creating an overall Medicare benefit to provide prescription drug coverage, I believe that allowing the safe reimportation of FDA approved prescription drugs, increasing access to generic prescription drugs and ending the price discrimination against Medicare beneficiaries and all American consumers is an immediate step towards achieving our desired goal of access to lower priced prescription drugs.

I am pleased to have had this opportunity to offer my testimony and look forward to working with the Committee on these critically important issues in the months to come.

PREPARED STATEMENT OF SENATOR SNOWE

Mr. Chairman, I want to thank you for inviting me to testify today before the Senate Health, Education, Labor and Pensions Committee. I appreciate the opportunity to share my thoughts with the Committee on the issue of prescription drugs.

Before I begin, I want to commend you, Chairman Jeffords, and the other members of the Committee for all of the work you do on health care issues. Health care has never been easy—it has never been “cut and dried” and it seems that there are often many options to consider. The so-called “re-importation” of prescription drugs is no different.

The United States is in the midst of a time of amazing prosperity. Nearly every week it seems that we hear of astounding new breakthroughs in biomedical research and in new prescription medications. And there is no question in anyone’s mind that we have the best—the very best—health care in the world.

But our health care system is not without its flaws. Prescription drugs are revolutionizing health treatments, but their high cost is causing concern throughout the country. Everywhere we turn—from “60 Minutes” to Newsweek—we hear of the struggles that our nation’s patients, especially the elderly, face, and the dramatic difference in costs of prescription medication between the U.S. and our neighbors to the North. The high cost of prescription medications in the United States is forcing many of our nation’s seniors to make unthinkable decisions that are harmful to their health and well-being. It is simply unacceptable that the elderly have to choose between filling a prescription or buying groceries.

A solution to the pressing problem of prescription drug coverage can’t come soon enough. In 1998, drug costs grew more than any other category of health care skyrocketing by 15.4 percent in a single year. And that’s a special burden for seniors, who pay half the cost associated with their prescriptions as opposed to those under 65 who pay just a third.

Seniors are reeling from the burden of their prescription drug expenses. The March/April 2000 edition of Health Affairs reports that the average senior now spends \$1,100 every year on medications. And with the latest HCFA estimates putting the number of seniors without drug coverage at around 31 percent of all Medicare beneficiaries—or about 12 out of nearly 40 million Americans—it’s not hard to see why we can no longer wait to provide a solution. In fact, nearly 86 percent of Medicare beneficiaries must use at least one prescription drug every day.

Who are these seniors who don’t have prescription drug coverage? Who are the ones traveling by the busload to Canada to buy their prescription drugs? These are people caught in the middle—most of whom are neither wealthy enough to afford their own coverage, nor poor enough to qualify for Medicaid. In fact, we know that seniors between 100 percent and 200 percent of the federal poverty level have the lowest levels of prescription drug coverage. And these seniors who are just over the poverty level are the least likely to have access to either employer-based coverage or Medicaid.

Today’s hearing on international pricing disparities and the safety issues surrounding prescription drug reimportation is yet another facet to the growing debate around the lack of meaningful drug coverage for our nation’s seniors.

In my eyes, it is absolutely unconscionable that any senior would be arrested after purchasing their otherwise legal prescription medication in Canada. That is why I have joined Chairman Jeffords as an original cosponsor of the “Medicine Equity and Drug Safety Act” (S. 2520). This bill will allow Americans to legally purchase in Canada a limited amount of their medication for personal use. In addition, pharmacists and wholesalers will be allowed to import prescription drugs for sale to American customers that were made in the U.S. or in FDA-approved facilities.

Opponents of the reimportation of prescription medications have well-founded concerns about the safety of these medications. There is no doubt that the U.S. Food and Drug Administration is the world’s premier agency in ensuring not only that drugs are safe and effective for their intended use, but that the actual manufacture of these drugs is done cleanly and safely.

So when Congress considers changing the law to allow the importation of either retail or personal use prescription medication, we must also consider the safety implications that are involved: Are other countries insisting on the same standards we are? Are other countries guaranteeing the effectiveness of the medication medication that is purportedly identical in strength? Are other countries using the same ingredients and ensuring that there are no impurities in these ingredients?

I believe the Chairman has been properly attentive to these safety considerations and has included substantial safeguards against the reimportation of lesser-quality prescription medication.

As with all health care issues there is another side to the issue of prescription drug importation besides the position of those who oppose reimportation due to safety or price control concerns—and this side is the perspective of the thousands of Americans who find themselves traveling across our border to Canada to purchase their prescription medications.

Clearly, seniors are traveling to Canada because the price of prescription medications is generally less expensive than in the United States. The difference in the prices between the Canadian and the American market for pharmaceutical products does not come because we are purchasing different drugs or different quantities of drugs. It is this very point that I hear about the most from my constituents: why can a person buy the same exact drug, in the same exact dosage, and the same quantity, for so much less in Canada than they can in Maine?

The disparity in costs between U.S. and Canadian drug costs reflects our different markets, but also the government-run health care system that limits choices and proscribes doctors and care for Canadian consumers. The Canadian health care system is a government-run monopoly, an approach soundly rejected by the American public in 1994. In the U.S., costs are constrained through the market—not by the government—as health insurers, pharmacy benefit managers, and preferred customers like the U.S. Department of Veterans Affairs negotiate heavy discounts based on the size of their insurance pool.

Seniors in the U.S. have limited bargain power to negotiate down drug costs because they are not part of a single pool. Yet if seniors were united in a single group, they could exercise substantial clout in the marketplace to negotiate lower drug costs.

There are 39 million Medicare beneficiaries—and these 39 million customers purchase a third of our nation's prescription medications. This represents a very large section of the market. Enacting prescription drug coverage for Medicare beneficiaries will make seniors a part of private-buyer groups with greater marketplace clout. This market force allows seniors as a group to negotiate discounted pharmaceutical costs that will not only be the most economically sound solution, but will also guarantee seniors coverage of their prescription drugs.

When American seniors find they have no market power, they often determine that their only recourse is to buy their much-needed drugs in a completely different market. It is fundamentally unfair when seniors in Maine, Vermont, or Minnesota feel they must drive across the Canadian border to obtain affordable prescription medications. And while it is illegal for Americans to go to Canada and purchase drugs to be brought back to the United States, we know that this happens on a daily basis.

Decriminalizing the practice of reimporting prescription medications is, at best, an interim approach. Frankly, I consider it an imperfect solution that can be implemented while Congress debates the larger issue of Medicare reform, and enacting meaningful prescription drug coverage for Medicare beneficiaries.

Yes, I agree that the prices of pharmaceuticals—and especially the rate at which they are increasing—are shocking. But even more shocking is that, in a time of astonishing pharmaceutical breakthroughs, outpatient prescription medications are not a guaranteed and integrated part of seniors' total health care.

But seniors should not have to worry about whether or not they can afford to fill a prescription their doctor fills out for them. Prescription drug coverage should be part-and-parcel of their integrated healthcare. Prescription drug coverage should be a complementary part of any medical therapy program recommended by their doctor.

Since the 106th Congress began, the Finance Committee has had 15 hearings on Medicare reform—three solely on the need to enact prescription drug coverage for

Medicare beneficiaries. There are several proposals that will provide prescription drug coverage for Medicare beneficiaries on the table—some of which are either authored or cosponsored by members of this Committee. One of these proposals, the Seniors Prescription Insurance Coverage Equity Act (S. 1480) I wrote with Senator Ron Wyden of Oregon.

Our plan will give seniors coverage options similar to those enjoyed by Members of Congress and other federal employees, through a choice of competing comprehensive drug plans. SPICE will prescribe prescription drug coverage for all Medicare-eligible seniors, with the federal government covering an or part of the premiums on a sliding scale.

SPICE has the advantage of working with or without Medicare reform something I've heard time and again is important to seniors. SPICE gives us the best of all

possible worlds—a system that can exist outside of Medicare reform, co-exist with a new Medicare regime when it comes, and actually serve as a downpayment on comprehensive reform.

Congress needs to address the lack of meaningful prescription drug coverage immediately, this year. The lack of prescription drug coverage is not an issue that goes away for seniors, despite the fact that they skip doses, break pills in half, or don't even fill their script in the first place. A person doesn't have diabetes or high blood pressure every other day. Seniors don't have the luxury to defer their illnesses, and Congress shouldn't have the luxury to defer action.

Mr. Chairman, I am pleased to be a cosponsor of your legislation, the Medicine Equity and Drug Safety Act. You have written a bill with the needs of American consumers in mind, and you are ensuring that Americans will have access to safe and affordable prescription medications while Congress works to devise a long-term solution to this very serious problem.

Mr. Chairman and members of the Committee, I thank you for the opportunity to address you this morning.

PREPARED STATEMENT OF SENATOR GORTON

Senator Jeffords thank you for holding this hearing today on prescription drug costs and safety.

You and I are troubled by the same paradox. The United States invents some of the world's most innovative and effective medicines that treat heart disease, ulcers, depression and a host of other debilitating and life-threatening diseases, yet these same medicines are priced much higher in the US than virtually anywhere else in the world. Many of our citizens can't afford the products that were discovered, developed and manufactured in the United States.

All of us have read accounts of Americans crossing our borders in order to buy vital prescription drugs at deeply discounted prices. Every day seniors and other Americans can save 50%, 60% or even 70% on their drug bills simply by going to Canada or Mexico. A busload of seniors from Seattle recently saved \$12,000 just by driving two hours north to buy their medications at a Canadian pharmacy. These savings are by no means unusual.

Here are just a few examples: The Pecks from Tacoma, Washington saved \$600 by going to Canada to buy a three month supply of blood pressure, stomach and sinus medications. Tamoxifen to treat cancer cost \$15 for a one month supply in Canada and \$95 a month in Vermont. Prozac to treat depression, is just .95 cents a pill in Mexico and costs \$2.21 per pill in the US.

My own office conducted a study and I was astounded to learn that for the top ten most commonly prescribed drugs, average prices are 62% lower in Canada than in Washington state.

Why are drugs so much less expensive in Canada, Mexico and other countries? A major reason for this disparity is that foreign governments have implemented price control policies that tempt successfully I may say—US drug companies to discriminate against American consumers. Other countries offer to pay the nominal costs of manufacturing a drug, some profit and little else. Our drug companies agree because they can still make a profit, leaving our citizens to pay the high costs associated with research and development of new drugs. According to the industry, the price other countries pay in no way compensates for the expensive research and development costs for new drugs. American consumers end up subsidizing the research and development for the rest of the world.

I believe it is time to change the law so that Americans are no longer discriminated against with respect to the cost of prescription drugs. My idea is to borrow from a law that has applied to interstate commerce within the United States for the last 60 years—the Robinson-Patman Anti-discrimination Act. That Act simply tells manufacturers that they can't act to undermine one business by selling the same product to a competitor at discounted rates, unless the price difference is due to legitimate quantity discounts.

My bill, "The Prescription Drug Fairness Act" takes these same principles and applies them to prescription drug sales overseas. Drug manufacturers would not be able to offer lower prices at the wholesale level in Canada, Mexico or any other country than they charge inside the United States.

Since 1936, the Robinson-Patman Act has established as a legal norm the concept of fair dealing in pricing by prohibiting unjustified price discrimination. The same principle of fair dealing should be applied to prescription drug sales to wholesale buyers in different countries.

What will this proposal mean? Once drug companies have the incentive to charge non-discriminatory prices overseas and other countries pay a fair share of drug re-

search and development costs—people in Washington state and across the country will pay lower prices for prescription drugs.

The drug companies have demonized my idea by labeling it "price control". If this is a price control then we have had price controls on every product sold in the US for the last 60 years. My bill in no way tells drug companies what they can or can not charge for prescription drugs. It simply says that they cannot discriminate against Americans.

The kneejerk response from industry to my idea, and quite frankly to most ideas that lower prices for consumers, is that it will hurt research and development. I believe drug companies should be able to recoup the research and development costs for both successful and unsuccessful drugs. But my constituents in Washington and other Americans should not be forced to pay all of those costs for the rest of the world.

When Americans pay higher prices at the drug store cash register, that is not the first time they subsidize the research and development of new drugs. Taxpayer dollars are used to fund the research conducted by the National Institutes of Health; much of the basic science conducted with NIH grants is then transferred to the private sector. Taxpayer money is also the major source of funds for training scientific personnel, scientists hired by the drug industry in large numbers.

According to a 1993 report by the Office of Technology, in addition to general research and training support, there are 13 programs specifically targeted to fund pharmaceutical research and development. That same report noted: "Of all US industries, innovation within the pharmaceutical industry is the most dependent on academic research and the Federal funds that support it."

And finally there are the tax breaks: for research and development, for orphan drug development, and possession tax credits for manufacturing drugs in Puerto Rico.

Let me be clear. I support America's significant investment in research and development. I have supported all of the programs I just spoke about including the National Institutes of Health and the Research and Development tax credit. I also agree that drug companies should be able to recoup costs associated with research and development. But I do not think that American consumers should be discriminated against by being the only ones to foot that bill. American consumers who already strongly support R&D efforts through their tax dollars should not have to pay for R&D costs again in the form of higher prices at the drug store. Under my proposal, all users, domestic and foreign, would pay a fair share of those costs.

Unfortunately I'm becoming more and more convinced that drug companies are satisfied with the status quo. They know that they can simply raise prices in the US, if other countries negotiate or regulate to win lower prices. American consumers should not be subject to this kind of price discrimination—especially for products that are vitally important to preserving their health.

Congress will continue the debate about adding a prescription drug benefit to the Medicare program. I believe we should do so. The Medicare program must be modernized to reflect the state of health care today.

Adding a drug benefit to Medicare, which the industry naturally supports because it expands its markets, does nothing to address the cost of prescription drugs for the 44 million uninsured Americans and does nothing to address the growing concerns of employers, health plans, and hospitals about rising costs associated with prescription drugs. As more and more people use prescription drugs, as new drugs are developed and as coverage for prescription drugs increase, drug costs take up more of overall health care spending. But drugs are also costing individual Americans more. Recently, Families USA released a study that showed the average cost of the 50 drugs most commonly used by seniors rose by 3.9%, outpacing the inflation rate of 2.2%. A study from the University of Maryland's Center on Drugs and Public Policy projects prescription drug expenditures will increase 15-18 percent annually. Total prescription drug expenditures could double between 1999 and 2004 from \$105 billion to \$212 billion.

I am convinced that we need to address the issue of price discrimination this year, not only for Medicare patients but for the health system overall. My idea is just one way to end the huge differences in prices paid by Americans and people living in other countries for the same prescription drugs—and to secure lower prices for American consumers. There are other ways to achieve the same goal. For example, the bill you have introduced Mr. Chairman and a similar bill introduced by Senator Dorgan would allow pharmacists and wholesalers to re-import medicines that are approved by the FDA and manufactured in FDA approved facilities. It is simply ridiculous that once those drugs leave our border they are instantly much, much cheaper. Your bill would allow pharmacists and wholesalers to pass discounted prices to their customers. While some have raised safety concerns about the practice

of re-importation, the Jeffords bill entrusts Secretary of HHS with maintaining the gold standard of safety established by the FDA. Both re-import bills should help to lower prices for American consumers and may pressure drug companies into offering American consumers lower prices on their own without having to resort to re-importation.

These are two good ideas that get at the price discrimination problem. I am not wed to any one proposal, but what I am committed to is ending this discriminatory practice against American consumers. I will gladly support any idea that one of my colleagues, the industry or anyone else comes up with that genuinely addresses this problem.

In the meantime, while seniors and health plans, employers, hospitals and others struggle with the growing cost of prescription drugs, the pharmaceutical industry has been among the most profitable US industries in the last five years, with year to year earnings growing by more than 10% and for some companies 20%. So far, they have refused to engage in this debate on pricing.

I hope they will change their minds. Right now the current system leaves the drug companies' best customers feeling like they've been ripped off. Bob Elmer from University Place, Washington recently wrote:

"I am a recently retired pharmacist . . . and have always been proud of the American pharmaceutical manufacturers and the role that they play in . . . the search for new and innovative entities that help us live not only longer, but better. As a matter of fact, I worked for a major manufacturer for some time.

I, like you, am outraged at the manufacturers practice of charging the American public more than the Mexican public or the Canadian public. What is their rationale for the price differences?

This overcharging is a black mark on this industry."

I couldn't agree more. Drug companies should no longer be allowed to discriminate against Americans by charging higher prices here at home than they do elsewhere in the world. My bill will end that discrimination. Americans should be able to buy the prescription drugs they need to stay healthy at an affordable price.

PREPARED STATEMENT OF CHRISTOPHER T. RHODES

I am Professor of Applied Pharmaceutical Sciences at the University of Rhode Island. I have worked for the past thirty years on the development and evaluation of drug products.

The US public can justifiably have a high degree of confidence in the quality of drugs, which are supplied under the orders of an appropriate prescription signed by a physician, dentist nurse practitioner or other authorized individual. There are three main elements, which are responsible for the sophisticated nature of our constantly improving system for monitoring the quality of pharmaceuticals. These elements are the Federal Food and Drug Administration (FDA), the United States Pharmacopoeia (USP), and quality assurance/quality control scientists employed by the pharmaceutical industry who perform standardized tests to evaluate drug quality.

FDA is an agency of the US Federal Government. It controls the access of new products to the US market of prescription drugs by requiring sponsors to submit either full New Drug Applications (entirely new products) or Abbreviated New Drug Applications (generic products which are essentially a copy of a product already on the market by an NDA approval).

The information required in a NDA or ANDA is very comprehensive and covers clinical, chemical, manufacturing and other aspects of the product. FDA investigators perform pre-approval inspection before a new product is approved.

USP is a not for profit, non governmental agencies recognized by the US Congress and about 30 foreign countries as providing official standards for drug substances, drug products and test methods. When a patient receives a bottle of tablets labeled Propanol 20 mg USP the designation USP indicates that the product is represented as complying fully with all the requirements (purity, potency, content uniformity, dissolution etc.) which USP has applied in the monograph of Propanolol tablets.

Pharmaceutical companies use tests specified by USP to evaluate the quality of the product, which they have manufactured and wish to release onto the market. Stimulated by their own desires for excellence and assisted by USP and FDA the level of performance achieved by persons working in Quality Control/Quality Assurance laboratories has generally reached a high level.

There are two very important processes operating in the pharmaceutical area, which impact dramatically on the quality of pharmaceutical products manufactured in different parts of the world. I refer to globalization and harmonization. Globalization is the process by which many small companies are taken over or vol-

untarily join up with larger companies. We have, within recent years, seen a steady increase in the number of large "supra-national" companies which operate in many parts of the world. Such companies naturally standardize product, manufacturing process and evaluation by quality assurance and quality control as rapidly as possible. I term such companies "supra-national" because whatever their origins may be they operate in an essentially non-national manner. Thus, SmithKline Beecham and Glaxo originally coexisted of separate US and UK companies with their own localized traditions. The present large company is becoming essentially supra-national in nature producing drug products in a standard manner to standard specifications, whenever possible, in many parts of the world.

Harmonization within the pharmaceutical industry has been catalyzed by the International Conference on Harmonization (ICH), which is greatly influenced by the Big Three pharmaceutical powers: the European Union, the United States and Japan. The regulators, pharmaceutical scientists and other who serve on ICH has made steady progress towards a uniform approach to evaluating the quality of drug products. For example, we now have accepted standard methods for determining the stability of pharmaceuticals and thus how to assign a shelf life to a product.

The methods we use to evaluate drug product quality continue to evolve both in the United States and elsewhere. For example, USP in its so-called Mailbox study has recently shown that product mailed to patients in the US can in some instances experience temperatures of 130°F for a number of hours. This stress could indeed have serious adverse effects on the quality of some drug products. FDA, USP and other are now giving increasing attention to monitoring the quality of drug product in channels of distribution (e.g. stored in warehouses, repackaged, and transported by truck).

A proposal to allow reimportation of prescription drugs quite naturally raises concerns about possible quality defects of such products. It would be naive to state that such products could never have any problems. Indeed, we know that even with non-imported product problems do occasionally occur and recall of unsatisfactory product is required.

The key questions which have to be addressed are: Can we identify re-imported product which is likely to have a level of quality equivalent to non re-imported product? "and" are re-imported products more susceptible to such problems as counterfeiting, tampering or transportation damage.

Certainly if a re-imported product is manufactured so as to be in full compliance with USP specifications by a company which operates in the US, Canada, and the EU where standards controlling manufacture (current Good Manufacturing Practice regulations) are based on very similar principles to those used in the US, there would, in my opinion, be little concern about an unusually high level of problems. Secondly, if the tamper evident seals are in place I can see no reason to believe that tampering or counterfeiting would be more likely than for product produced in the US. An evaluation of the paper work pertaining to the imported material could also be most useful.

Having worked as a consultant and expert advisor for both USP and FDA, I can state unequivocally that I have every confidence in one or both of those entities developing, if necessary, a procedure for evaluating the quality of samples of re-imported product should that be thought to be desirable. The FDA Saint Louis Laboratory has quite rightly established an international reputation for top quality pharmaceutical analysis. Similarly, Dr. Richard Lindauer at USP has facilities and staff fully qualified to perform such work. I believe that the cost of these evaluations would be moderate. Consideration could be given to using a User Fee approach.

Concern may be raised that the age of re-imported product could be significantly greater than other product. However, as long as the product is still well within its approved shelf life this will not be a problem.

In conclusion it is my considered professional opinion that the process of using re-imported prescription drugs in the United States need not place the American public at any increased risk of ineffective or dangerous products. I further believe that USP and FDA do possess the necessary personnel, equipment and expertise so that samples of re-imported products could be subjected to appropriate laboratory testing should such action be thought necessary.

PREPARED STATEMENT OF PATRICIA M. DANZON

Good morning, Mr. Chairman. I appreciate the opportunity to address the Committee today. My name is Patricia Danzon, I am the Celia Moh Professor of Health Care Systems, Insurance and Risk Management at the Wharton School of Management at the University of Pennsylvania. I have a Ph.D. in Economics from the University of Chicago. Since 1985 I have done research and taught courses in Health

Economics, Pharmaceutical Economics and Management, and Comparative Health Care Systems at the Wharton School, at the undergraduate, MBA, PhD and Executive levels. Today I would like to summarize the findings of my research on international price differentials for pharmaceuticals, why most comparisons are biased, reasons for the differentials, and the implications of allowing importation of lower cost drugs from other countries.

Most studies of cross-national price differences for pharmaceuticals have led to the consensus view, that drug prices are much higher in the U.S. than in other countries. For example, the U.S. General Accounting Office (GAO, 1992, 1994) concluded that prices in the U.S. in 1992 were 32 percent higher than prices in Canada and 60 percent higher than prices in the U.K. A recent U.S. study (Minority Staff, 1998) reported that drug prices in the U.S. were 70 percent higher than in Canada and 102 percent higher than in Mexico. These studies have contributed to proposals to control U.S. drug prices. Some proposals would limit U.S. prices to no more than prices charged in Canada or other nations. Others would accomplish this goal by lifting restrictions on importing medicines from outside the U.S. These proposals are based on a misunderstanding of the facts, the economics, and their potential negative impact on patients both here and abroad.

BIASES IN PREVIOUS PRICE COMPARISONS

It is true that prices of many brand name drugs are lower in Canada and other countries than in the U.S. But the perception that U.S. prices on average are much higher than other industrialized countries is based on inaccurate and biased comparisons. Most price comparisons use small, unrepresentative samples and faulty methods—for example, a simple average of ten leading branded products—that lead to biased conclusions. The fundamental difficulty in doing drug price comparisons is that the mix of drugs available and their use vary widely across countries. For example, our analysis found that over 40 percent of drug sales in Germany, France, Italy and Japan were for molecules that were not sold in the US. Even when the same molecule is available, it may be sold in different dosage forms, strengths, packs and by different manufacturers. Moreover, the relative prices of different drugs vary widely—for example, one product may cost 50 percent less in Canada, another may cost 50 percent more. Valid comparisons should therefore be based on large, representative samples of products, including generics, and should use standard, weighted price indexes, which weight the prices of individual products to reflect their relative importance in overall consumption (see, for example, Diewert, 1987).

Most previous comparisons violate these basic principles of price comparisons. They use a small number of leading, branded products, excluding all generics, although generics account for over 40 percent of prescriptions in the U.S. They use a simple unweighted average of the price relatives, although such measures are extremely sensitive to the sample and generally give undue weight to the highest priced products. Some studies use retail-level prices and then draw conclusions about manufacturer-level prices. But retail prices include wholesale and retail pharmacy margins, over and above the manufacturer price, and do not reflect manufacturer rebates given to managed care and government purchasers. Hence comparisons based on retail prices cannot provide an accurate measure of differences in net prices to manufacturers.

ANALYSIS OF PRICES IN SEVEN COUNTRIES

Our study of drug prices in seven countries (Danzon and Chao, 2000) analyzed comprehensive 1992 data on manufacturer prices for outpatient sales, including brand and generic products, all formulations and packs. We compute several price indexes using standard index number methods, which weight prices of individual products to reflect their relative importance in overall consumption. We report price differences for two measures of price, price per dose and price per gram of active ingredient.

Table I shows the resulting measures of the average price differentials (percentage difference) for each country relative to the U.S. with prices weighted to reflect U.S. consumption. Numbers greater (less) than one imply foreign prices higher (lower) than the U.S. Using price per dose, the average price differentials relative to the U.S. are: Canada +2.1%, Germany +24.7%, France -32.2%, Italy -12.9%, Japan -11.6% and the U.K. 16.6%. Sweden and Switzerland were also higher than the U.S. on average, but are omitted from this study because of their small market size. These measures overstate manufacturer prices for the U.S. because they do not reflect discounts and rebates given to managed care and government purchasers.

Although the magnitude of price differences between the US and other countries may have changed since our 1992 data, the general conclusion almost certainly still

holds, that the widely cited comparisons based on a few, leading branded products provide a biased measure of overall average price differences. For example, our measures for 1992 show Canada 2.1 percent higher and the U.K. 16.6 percent lower than the U.S., whereas the GAO studies done at the same time reported the U.S. 32 percent higher than Canada and 60 percent higher than the U.K., using smaller, less representative samples and either no weights (GAO Canada comparison) or imperfect weights (GAO U.K. comparison).

A second important conclusion of our analysis is that there is no single, "right" measure of cross-national price differences for drugs. It is not the case that one country's drugs are all, say, 20 percent cheaper than another's—rather, the relative prices differ greatly across drugs. Because the mix of drugs and their relative prices are so different across countries, overall average measures of price difference vary, depending on the sample of drugs used, which country's consumption is used for quantity weights, and whether price is measured per dose or per gram. In general, for each country it is probably most appropriate to use its own quantity weights. Although there is no perfect measure, our indexes which are based on comprehensive data for all matching compounds, at manufacturer price levels and with U.S. quantity weights are more robust than previous comparisons that are based on very small, unrepresentative samples, confined to leading branded products, excluding all generics, with only one pack per product included and unweighted averages.

Our research also examined the extent of competition under alternative regulatory regimes, and the contribution of competition and other factors to cross-national price differences. We found that, in general, government price controls undermine price competition, particularly post-patent competition between generics and branded products, denying foreign consumers some of the benefits that American consumers enjoy. The U.S. has more generic competitors per compound, on average. This does not simply reflect the larger market in the U.S.—the U.S. has fewer total molecules than Germany, Italy and Japan. Price competition between generics is also more aggressive in the U.S. than other countries—indeed, countries with the strictest price or reimbursement regulation, such as France, Italy or Japan, have few generics and no effective generic competition. Yet competition for patent-expired drugs already yields large savings to U.S. consumers and this off-patent share is expected to grow as patents expire on many of the current leading drugs. Regulation of manufacturer prices is often also associated with regulation of retail pharmacy. This undermines retail pharmacy competition, particularly in over-the-counter (non-prescription) products, which also offer significant savings to U.S. consumers.

FACTORS CONTRIBUTING TO PRICE DIFFERENCES

Before discussing factors that contribute to international price differences for drugs specifically, it is important to note that price differences for physician and hospital services are often at least as large, reflecting differences in income levels; the structure, culture and norms of their health care systems; and insurance and regulatory systems. My discussion here focuses on drugs.

For developing countries, lower prices may reflect their much lower per capita income. In addition, weak intellectual property protection results in copy products that can sell for very low prices because they avoid the costs of R&D and may be manufactured to lower quality standards than U.S. originator drugs that incur high R&D costs and must meet FDA requirements for good manufacturing practices (GMP).

For industrialized countries at similar income levels to the U.S., price differences partly reflect differences in health care systems, including regulatory strategies. Most countries regulate manufacturer prices for drugs, either directly (France, Italy) or indirectly through controls on reimbursement (Germany, Japan) or rate of return on capital (the U.K.). The Canadian federal government controls launch prices for innovative brand products and limits post-launch price increases; provincial governments have significant monopsony (large buyer) power in operating their formularies; former compulsory licensing provisions may serve as a residual threat; and lower liability threats contribute to lower prices (Manning, 1997). Countries that traditionally regulated drug prices have generally found that price controls alone do not control rising drug expenditures, which primarily reflects volume growth, as physicians/patients switch to newer products, which are usually improved and higher priced than older products. Thus these countries superimpose limits on volume or on total drug spending, with similar "silo" budgets for other components of health care. This approach may hold down nominal prices and drug expenditures, but it distorts incentives for efficient coordination of medical services, hence in the long run cannot deliver maximum value for money spent.

Retail price differences, which motivate the bus trips to Canada, overstate the differences in net prices to manufacturers and insured U.S. consumers. U.S. consumers who are covered by pharmacy benefit management plans (PBMs) pay lower prices than cash-paying customers, because PBMs negotiate discounts on drug prices from manufacturers and on pharmacy margins from retailers. These savings may be passed on to consumers in lower insurance premiums or greater benefits, so the pass-through is hard to measure. However, the net cost to insured U.S. consumers and net revenue to manufacturers is certainly lower than is implied by comparisons based on retail prices to cash-paying customers. Since competitive manufacturer rebates to PBMs are likely to be larger for mature products in crowded therapeutic categories and these are precisely the drugs that are included in most drug price comparisons, comparisons based on retail prices for these mature products are likely to yield particularly biased estimates of net manufacturer price differentials.

Finally, current price differentials reflect movements in exchange rates. Most regulatory systems do not allow post-launch price increases. Thus even if a product is launched at the same price in the US and some foreign country, movements in exchange rates lead to price divergence over time.

PROPOSALS TO ALLOW IMPORTATION OF DRUGS

Proposals for importation of drugs from abroad into the U.S. raise issue of safety and of economic impact. My comments focus primarily on the economic effects of permitting third parties to import cheaper products from abroad into the U.S.

Leaving aside issue of counterfeits and safety, the main economic concern is that importation would shift product sourcing to the lowest-price foreign country, and this would have a very significant negative effect on global revenues of pharmaceutical companies and hence on R&D. The U.S. market accounts for over 30 percent of global drug sales and a larger percent of sales for U.S.-based firms. Hence lower U.S. prices would significantly reduce total revenues and hence incentives for R&D. Moreover, permitting importation by third parties of on-patent products would significantly undermine traditional patent protection. If this weakening of intellectual property protection were to spread to other countries, this could further lower prices abroad. Currently, the European Union (E.U.) permits so-called parallel trade within the E.U. but does not permit importation of on-patent drugs from countries outside the E.U.

Trade normally increases consumer welfare, by shifting supply to the country that is the most efficient supplier, thereby permitting consumers in other countries to benefit from lower prices. However, such efficiency gains are small if any, in the case of trade in pharmaceuticals, because the lower prices in the exporting country primarily reflect greater regulatory leverage, not lower real costs of production. Of course, if manufacturers in the exporting country are not held to the same quality and good manufacturing standards as U.S. manufacturers, this could be another factor contributing to trade but would be harmful to U.S. consumers. Furthermore, although trade usually benefits consumers, in the case of trade in pharmaceuticals the savings may accrue largely to intermediaries—wholesalers or pharmacists—not as lower prices to consumers, at least in the short run.

More fundamentally, given the cost structure of the research-based pharmaceutical industry, trade is likely to actually reduce economic efficiency. This is the result of the interaction of two factors: the cost structure that includes a very significant level of global joint costs, and national systems of price regulation that exploit government's monopsony (large buyer) power. Global joint costs are costs that jointly benefit many consumers worldwide; these costs are independent of how many or which countries are served and hence cannot be attributed to specific countries. Pharmaceutical R&D is largely a global joint cost. It accounts for roughly 30 percent of the total cost of bringing new drugs to market if all costs are calculated in discounted present value (Danzon, 1997a).

Although joint costs, by definition, are not attributable to any specific set of consumers, somehow consumers overall must pay these costs if R&D is to continue. Economists have addressed the question of how to set prices to different users in order to cover joint costs, while yielding the highest social welfare. The resulting theory—so-called Ramsey pricing—implies that charging different prices is appropriate when consumer groups differ in their true price sensitivity (Ramsey, 1927; Danzon, 1997b). Price differentials lead to more efficient use of the product and a more efficient level of R&D than would a policy that results in uniform prices to all consumers.

Price differences do not imply cost shifting, contrary to widely held beliefs. On the contrary, the prices required in high-price countries to support a given level of R&D are lower if low-price countries remain in the market, paying prices that are suffi-

cient to cover their country-specific marginal cost and make some contribution to joint costs, rather than being priced out of the market by a uniform higher price. Such differential pricing, based on price sensitivity of different customers is likely to become the norm for computer software and Internet services which, like pharmaceuticals, have high fixed costs of development but very low marginal costs of production. For firms with this cost structure, marginal cost pricing is not viable because it does not cover the fixed costs of product development.

The problem of recouping joint fixed costs of R&D is not unique to pharmaceuticals and is addressed through our system of patents. Patent protection is intended to enable innovators to charge prices above the marginal cost of production, in order to cover their R&D investment. Patent protection traditionally bars the sale of copy products during the life of the patent, including importation of the same product from abroad. The value of patent protection for pharmaceuticals is already significantly constrained in many countries by price regulation. Permitting trade in on-patent products magnifies this effect, by letting the low prices in one country spill over to other countries.

In countries with national insurance programs where the government is a monopsony (sole) purchaser of medicines, each government faces a strong temptation to force prices down to the marginal cost of supplying that country, free riding on others to pay for the joint costs of R&D. This strategy is attractive to buyers because the joint costs are sunk by the time prices are negotiated, and companies are willing to supply existing products as long as prices cover the short run marginal cost of production and distribution. However, if each country pays only its country-specific marginal cost—either through direct regulation or by importing low prices from other, lower-price countries—then no one pays for the global joint costs of R&D. In the long run consumers will be worse off because they will not have access to some of the innovative pharmaceuticals that they would have been willing to pay for. (Willingness to pay is defined here to include both private and community (social solidarity) willingness to pay for others). At the limit, if prices are suppressed to the level of country-specific short run marginal cost in all countries, the revenue shortfall could be as high as 50-70 percent of the total cost of bringing new pharmaceuticals to market.

As trade and/or regulation based on foreign prices lead to the break down of separate markets for drugs and a downward convergence of prices, economic theory predicts that manufacturers will adjust their pricing strategies by attempting to charge a single price in all connected markets, in order to eliminate the price arbitrage opportunity. Several multinational companies already attempt to set launch prices within narrow bands in all countries of the EU, despite significant differences in income levels and health care systems. If the U.S. were linked to foreign markets, either by trade or by regulation based on foreign prices, poorer nations would inevitably see prices rise or drugs not launched at all. This clearly hurts patients in those nations but would also harm patients here. For each sale today, even at a price below a U.S. market price, revenues continue to exceed marginal production costs. Were these sales not made, overall revenues from these countries would decline. Thus in the long run U.S. consumers will also lose. The uniform price policy leads to lower global revenues and hence some innovative medicines will not be developed that consumers would have been willing to pay for.

These considerations imply a strong argument, based on economic efficiency and one definition of equity, for not permitting trade in industries that are characterized by high global joint costs of R&D, importance of patent protection and exposure to price regulation abroad. These are precisely the characteristics of the pharmaceutical industry. Whether the current level of R&D is too high or too low is impossible to tell. Unfortunately, price regulation will not simply eliminate drugs that, ex post, seem to be "me toos". If on balance we are satisfied that the new drugs that are being developed are worth paying for, then policies designed to import lower foreign prices are ill-advised.

REGULATION VS. COMPETITION

Just as some price differences exist today between the U.S. and other nations, differences also exist within the U.S. This is good news, not bad. The fact that today large managed care customers are able to negotiate price discounts confirms that competition can effectively work to restrain prices if given the chance. The U.S. competitive model, which results in higher prices for some innovative, on-patent product but aggressive generic entry and price competition once patents have expired, yields average costs that are similar to some other countries but much stronger incentives for innovation than regulatory systems that constrain prices for innovative drugs and also undermine competition from generics. The real problem in U.S. pharma-

ceutical markets is distortions to competition, not any intrinsic market failure that could or should be "fixed" by regulation.

As in other industries, all health care providers and suppliers, including drug manufacturers, charge lower prices to more price sensitive customers—typically managed care buyers. Managed care's ability to steer patients towards lower cost providers makes managed care demand more price sensitive. In the case of managed pharmacy benefits, formularies of preferred drugs and structured co-payments are used to shift market share to manufacturers that give discounts, just as physicians, pharmacists and hospitals give discounts in order to be in preferred provider networks. The rapid growth of managed pharmacy benefits suggests that patients view the minor restrictions on choice as well worth the savings.

The real problem that policymakers need to address is that seniors and others who do not participate in managed plans do not enjoy the same benefits of competition as those who do. The best solution is to deal with this as an insurance problem, enrolling Medicare and Medicaid beneficiaries in competing plans that manage their pharmacy benefits to take advantage of price competition. Since health plans must compete for consumers, formulary design cannot ignore consumer preferences, unlike regulatory alternatives. Social concerns can be addressed through risk-adjusted premiums, or tax credits to address equity and affordability concerns.

In addition, we have recently seen partnering initiatives by two leading pharmacy benefit managers, Merck-Medco Managed Care/Reader's Digest and PCS/AARP, to extend discount prices to consumers who are not enrolled in managed health plans. These and other competitive insurance-based approaches, which are grounded in basic economics, are at least worth trying before turning to regulatory alternatives, including importation, which could seriously distort the working of markets and undermine R&D. If we want affordable drugs and the level and type of R&D that consumers and taxpayers, on average, are willing to pay for, then the best approach is to permit market-determined prices within the context of competing health plans and to permit international price differentials.

PREPARED STATEMENT OF RONALD F. POLLACK

Mister Chairman and Members of the Committee: Thank you for inviting me to testify today. Families USA is a national non-profit organization dedicated to protecting and improving the health care of consumers. We have been engaged in analyzing the implications of changes in the Medicare program on Medicare beneficiaries for some time. Our most recent research efforts have focused on examining the prices of prescription drugs and what impact those rising prices have on prescription drug coverage for Medicare consumers. This testimony will describe what we have learned about drug prices. The bottom line is that seniors need help to buy the drugs they need. A sound public policy will ensure that seniors gain the benefit of two basic policy changes, Medicare coverage of prescription drugs and reasonable steps to ensure that drug costs are moderated.

Medicare beneficiaries are the only insured population group without prescription drug coverage. At any point, approximately 35 percent of all Medicare beneficiaries are without drug coverage. Over the course of the year, nearly half of all Medicare beneficiaries are without drug coverage for all or part of the year. (See Appendix 1.) Based on recent trends, it is likely that this situation will get worse. Among the primary sources of prescription drug coverage for those beneficiaries who have it—Medigap, Medicare+Choice, and employer-sponsored coverage—drug coverage is increasingly unaffordable and unreliable.

Medigap: Individually purchased Medigap policies cover a relatively small number of Medicare beneficiaries, roughly 3.3 million beneficiaries (or about eight percent of all Medicare beneficiaries). Given the additional cost of a prescription drug policy, it is understandable why a senior living on a fixed income does not see this as an affordable option. Looking at the average cost of Medigap policies with and without prescription drug coverage, the cost differential clearly illustrates why few people purchase plans with drug coverage. Simply put, the costs of the plans with drugs are considerably more expensive—substantially as a result of adverse selection.

If you compare premiums for two moderate policies (of the ten standardized plans)—plans letters E and H, where the only significant difference in coverage is that the latter covers drugs and the former does not—you will see an annual premium difference of approximately \$600. Even so the drug plan is sparse. The drug benefit under plan H has a \$250 deductible, a 50 percent copayment, and a cap of \$1250—coverage that still leads to significant out-of-pocket costs for beneficiaries. The premium differential is considerably larger for plans with more considerable health coverage. The difference between Plan F (without drug coverage) and Plan

J (with drug coverage) is more than \$1,700 per year. Clearly, for many, the premiums for Medigap drug plans are unaffordable (see Appendix 2).

Medicare+Choice: Approximately 13 percent (5.2 million) Medicare beneficiaries had some prescription drug coverage through a Medicare+Choice plan. However, Medicare+Choice plans are an increasingly unreliable source of prescription drug coverage for seniors because plans covering prescription drugs are not offered consistently across the country and the benefits they offer are being reduced. In 2000, beneficiaries in four states (AR, IO, NE, and WV) have no access to plans offering drug coverage. In an additional four states (DE, LA, NM, and NC), beneficiary access to plans with drug coverage decreased significantly.

Obviously, as health plans drop out of Medicare+Choice, the availability of prescription drug coverage is jeopardized. For those beneficiaries who do have access to plans with drug coverage, the value of the drug benefit is decreasing. Between 1999 and 2000, the proportion of plans with benefit caps of \$500 increased by 50 percent. During the same period, the number of beneficiaries living in areas with copayments on brand name drugs averaging at least \$25 more than tripled. Recent announcements from two major Medicare+Choice plans suggest beneficiaries will have fewer options in 2001. Cigna Corporation recently reported it will no longer serve Medicare markets in 11 states beginning January 2001. Aetna Inc., will also terminate its participation as a Medicare+Choice provider in a number of markets in January 2001.

Employer-Sponsored Retiree Coverage: Employer-sponsored retiree coverage is declining, leaving more Medicare beneficiaries on their own to purchase coverage or to pay for drugs out-of-pocket. Among large firms of 1,000 or more, the percentage of large firms offering retiree coverage dropped from 80 percent in 1991 to 67 percent in 1998. The trend is the same across firms of all sizes. According to a recent Mercer Foster-Higgins survey, the percentage of firms offering retiree coverage dropped from 40 percent in 1994 to 28 percent in 1999. Thus, employer-sponsored retiree coverage—which has been the most significant pathway to drug coverage for seniors—is diminishing rapidly (see Appendix 3).

RISING PRICES AND THE IMPACT ON SENIORS

Seniors without drug coverage are most affected by rising prescription drug prices. In November 1999 Families USA released a report looking at prices of the 50 top-selling drugs for seniors. The report found that prices of these 50 top-selling drugs rose much faster than inflation. In April we released an updated version of that report, "Still Rising: Drug Price Increases for Seniors 1999-2000." Among the 50 top-selling drugs for seniors, there was some good news and some bad news. The good news for the 1999-2000 period was that the prices of 12 of the 50 drugs rose slower than inflation—with nine of those not increasing in price at all. The bad news was that 33 of the 50 drugs rose in price at least one and one-half times inflation. Half of the drugs rose at least twice as fast as inflation. Sixteen drugs rose at least three times inflation and one-fifth (11) rose at least four times the rate of inflation (see Appendix 4).

Some drugs are rising at much faster rates. For example, the price for furosemide, a generic drug, rose 50 percent in this one year. Klor-con 10, a brand name drug, rose 43.8 percent (see Appendix 5).

The report also compared prices over the six-year period of 1994-2000. Thirty-nine of the 50 drugs were on the market for the full six years. Of those 39 drugs, prices for 37 rose faster than inflation (see Appendix 6). Prices for three-fourths (30) rose at least 1.5 times inflation. Over half (22) rose at least twice as fast as inflation and over a quarter (11) rose at least three times the rate of inflation. Six drugs rose at least five times the rate of inflation. Examples of some of the faster growing drugs include lorazepam (which rose 409 percent, or 27 times inflation) and furosimide (which rose 210 percent, or 14 times inflation). (See Appendix 7.)

While these price increases may seem dramatic, the impact on seniors is clear when we look at two examples:

For a widow or widower with a gastrointestinal problem, the drug most likely to be prescribed is Prilosec. Based on 1998 data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program (the largest outpatient prescription drug program for older Americans), Prilosec is the second highest of all the top-selling drugs prescribed for seniors. The annual cost for a senior with no drug coverage taking Prilosec (20 milligram, controlled release capsules) is \$1,455. For a widow or widower subsisting at 150 percent of poverty (\$12,525 of income per year), the annual cost of Prilosec alone will consume more than one in nine dollars (11.6 percent) of that senior's total budget. Even at twice the poverty level (\$16,700

per year), Prilosec will consume almost one out of eleven dollars (8.7 percent) of that widow's total income (see Appendix 8).

The second example is a senior with no drug coverage who has diabetes, hypertension, and high cholesterol—three conditions that often occur in conjunction with one another. A widow with these three conditions is likely to be treated with Gluophage, Procardia XL, and Lipitor. Annual costs for Gluophage (500 milligram tablets) will be \$708. Annual costs for Procardia XL will either be \$521 or \$901, depending on whether 30-milligram tablets or 60-milligram tablets are prescribed. The annual cost for Lipitor (10 milligram tablets) will be \$686 (see Appendix 9).

Thus, total annual spending for seniors with diabetes, hypertension, and high cholesterol—for these three drugs alone—will range from \$1,915 to \$2,295. For a widow subsisting at 150 percent of poverty, this expenditure will constitute as much as 18.3 percent of her annual income. Even at twice the poverty level, these costs will consume up to 13.7 percent of her annual income. These costs, therefore, are likely to cause significant economic hardships.

Clearly, affordability of prescription drugs is a problem. Coverage for prescription drugs, for those people who have it, makes a difference as to whether or not seniors get the drugs they need. In 1996, seniors with drug coverage obtained, on average, 21 prescriptions, while those without drug coverage received only 16 prescriptions (see Appendix 10).

PAYING MORE FOR PRESCRIPTION DRUGS IN THE U.S. THAN IN OTHER COUNTRIES

It is clear that drug prices are much higher in the United States than they are in other countries. Several months ago USA Today compared prices in the U.S., Canada, Great Britain, and Australia for the ten best-selling drugs. The comparison found that Prilosec was two to two-and-one-half times as expensive in the U.S.; Prozac was two to two-and-three-quarters as expensive; Lipitor was 50 to 92 percent more expensive; and Prevacid was two-and-one-third to four times more expensive. Only one drug was cheaper in the U.S. than in the other countries, Epogen. In the case of all other ten drugs, the U.S. price was highest, by far (see Appendix 11).

Two General Accounting Office studies from 1992 and 1994 show similar results. Comparing prices for 121 drugs sold in the U.S. and Canada, prices for 98 were higher in the U.S., and almost half were more than 50 percent higher. Comparing 77 drugs sold in the U.S. and in the United Kingdom, 86 percent of the drugs were higher in the U.S. and more than 60 percent were more than twice as high in the U.S.

THE R&D DEFENSE IS A CANARD

The pharmaceutical manufacturers argue that they need these higher prices so they can undertake research and development. They say that, if we reduce these prices, research and development will be curtailed. The drug industry's assertion in this respect is wildly exaggerated. Among the top pharmaceutical companies, more money goes for marketing, advertisement, and administration than for research and development. More money is received in profits than is spent on research and development. In 1999, among the five companies with the highest revenues, four spent at least double on marketing, advertising and administration than was spent on research and development. For example, Merck spent considerably more than twice as much on marketing, advertising, and administration than it did on research and development. Comparable comparisons apply to other large pharmaceutical companies. Indeed, for the ten companies with the highest revenues (for which data are available), only one reports spending more on research and development than on marketing, advertising, and administration. Merck's profits for that year were approximately three times its research and development budget (see Appendix 12).

For the manufacturers of the top 50 drugs sold to seniors, profit margins are more than triple profit rates of other Fortune 500 companies. These drug manufacturers are receiving an 18 percent profit rate of total revenues compared to approximately five percent for other Fortune 500 companies (see Appendix 13). Given their profit margins and advertising budgets, it is a wild and irresponsible exaggeration for pharmaceutical companies to suggest that, if prices were moderated, the first and only place they would cut is their research and development budget.

The pharmaceutical manufacturers are quick to overstate the role they play in research and development and to understate the role the government plays in this area. According to a study conducted by MIT and cited in the New York Times, of the 14 most medically significant drugs developed over the past 25 years, 11 have roots in research funded by the government. In general, much of the basic research essential to the development of new drugs is conducted at NIH or funded by the government. Taxol and Xalatan are examples of drugs developed from basic research

conducted by the government. These two drugs alone now earn their manufacturers, Bristol-Myers Squibb and Pharmacia, hundreds of millions of dollars annually (see Appendix 14).

It is amusing to see how the pharmaceutical industry has a love-love-love-love-hate relationship with the US government. On the one hand, the industry loves the advantages gained through NIH research, patent protections, and laws governing re-importation. In addition, the industry loves the multiple tax advantages it receives, including the research and development tax credit and tax breaks for manufacturing in Puerto Rico. On the other hand, they continue to object to any effort by the government to moderate prices for the population most in need of drugs, the seniors and persons with disabilities in Medicare.

The rising prices of prescription drugs in the U.S. and the difference between what consumers pay in the U.S. compared to other countries raises real questions about equity and fairness of the drug industry's pricing practices. However, the best protection for consumers against high prices is to have guaranteed coverage that uses market clout to moderate drug prices and helps consumers pay for these drugs.

RECOMMENDATIONS FOR AFFORDABLE DRUGS FOR SENIORS

A sound public policy will ensure that seniors gain the benefit of two basic policy changes, Medicare coverage of prescription drugs and reasonable steps to ensure that drug costs are moderated. The principles for those changes include:

Coverage must be a defined benefit (both basic and catastrophic) included in Medicare, not the promise of access to a private insurance policy: Prescription drug coverage should be added to the Medicare benefits package in such a way that beneficiaries have the same guaranteed coverage for drugs that they have today for hospital, physician and other Medicare covered services. Public policy predicated on the availability of private-sector drug-only insurance will be a mirage for most seniors. Insurance companies are unlikely to provide such coverage, and the premiums would quickly be unaffordable due to adverse risk selection.

Prescription drug costs must be contained: A Medicare drug benefit will not be affordable if it does not include efforts to contain prescription drug costs. There are a number of mechanisms that Medicare can use to contain costs but Medicare should use its size to leverage the lowest price possible.

The Medicare benefit must be affordable to all seniors, with special subsidies for low-income beneficiaries: The Medicare benefit must offer coverage that is affordable, including reasonable premiums and coinsurance requirements, and it should include catastrophic protections. Poor and near-poor Medicare beneficiaries should receive special assistance in paying for their premiums and out-of-pocket expenses. Low-income beneficiaries should have the premiums fully subsidized and should also receive help with any coinsurance requirements.

Administration of low-income protections should be improved: The low-income assistance component of Medicare should eventually be integrated into the Medicare program, including full federal funding and federal administration of this benefit. It makes little sense to foist responsibilities of low-income protections on the states through Medicaid.

In conclusion, we hope to work with members of this committee and the rest of the Congress to make a prescription drug benefit in Medicare a reality.

[Additional material may be found in committee files.]

PREPARED STATEMENT OF PAUL ABRAMS

Mr. Chairman, Members of the Committee, thank you for the opportunity to testify today on a subject of major importance to the health and welfare of our citizens. I am testifying on behalf of the Biotechnology Industry Organization (BIO), a trade group representing more than 900 biotech companies, universities, research institutions, state biotechnology associations and affiliates in 49 states.

I am Paul Abrams, Chief Executive Officer of NeoRx Corporation. We are located in Seattle, Washington, an area that is home to a large and growing number of biotechnology companies, as well as the University of Washington and the Fred Hutchinson Cancer Research Center where many technological advancements have pioneered bone marrow transplantation.

NeoRx employs 65 people. We focus on cutting-edge, innovative ways to treat cancer. In May we reported at the American Society of Oncology Meetings that 18 of the first 40 patients evaluated in our clinical trial achieved complete remissions of a form of cancer called multiple myeloma which afflicts 15,000 new patients per year in the United States alone, many of them over 65 years old. A Phase III trial, the last stage of clinical testing prior to submitting for approval, is due to begin in the next several months. A Phase I trial of this same drug of prostate cancer and

in breast cancer patients should begin this summer. Additional cancer therapies that have also shown early promise are slated to begin testing later this year and next year.

Let me begin by stating unequivocally that we in the Biotechnology Industry take very seriously the issue of providing seniors access to drugs at affordable prices. Because my company, like most in the biotechnology industry, has not yet achieved a drug approval, I am really here to represent those future patients and future products that have no other present constituency.

We believe that solutions involving any scheme that includes price controls, direct or indirect, are inadequate, unnecessary and counterproductive.

Any remedy involving any scheme that includes non-market oriented price controls is counterproductive.

We applaud the efforts of this committee and others in Congress for raising the critical matter of improving seniors' access to medicines, but we must be certain that the most life-enhancing and cost-effective therapies for seniors and others—future breakthrough products for diseases such as cancer, osteoporosis, Alzheimer's disease, Parkinson's disease, diabetes, heart disease, stroke, Lou Gehrig's disease and others—that are currently being researched and developed by biotechnology companies do not become the unintended victims of well-intentioned, but inappropriate solutions to that problem. To do so would make permanent the high total costs of care these and other diseases engender. To do so would confine people forever to the pain and suffering associated with these illnesses. To do so would be to deprive our citizens, present and future, of the fruits of the revolution in biological sciences spawned three decades ago. You have all heard the poignant eloquence of Christopher Reeves about the prospects for him, and others, that this research will, with time and sufficient resources, provide.

Research and development of safe and effective agents, however, is an expensive and time-consuming process, requiring tenacity and patience from researchers, from companies' and from their investors! Risks of failure are high and the road to most new medication is littered with the broken test-tubes, discarded case report forms and rejection letters from regulators of earlier, failed attempts.

Ideally, a prescription drug benefit would occur in the larger context of Medicare modernization.

BIO agrees that seniors and Medicare eligible disabled people need improved access to prescription drugs. BIO member companies have been actively working with legislators to craft legislation addressing this problem.

The best way to provide affordable access is to offer coverage. Federally imposed discounting proposals of any stripe may in the short run help achieve a small percent decrease in drug costs, but coverage will help seniors more. The distinction between discounting and coverage can mean the difference between 10-15 percent off a \$3,000 outpatient prescription drug or a \$10 to \$15 co-pay for that same product.

Anything, that even smacks of non-market oriented price controls will be viewed, properly, as the nose-under-the-tent for more such 'fixes' in the future, drying up the sources of investment, both internally within companies and, critically, from outside investors. This money is absolutely required to bring highly valuable improved therapies to market. BIO urges the Senate to support approaches that will both help seniors gain access to today's treatments and permit them and their children to access tomorrow's cures.

The system of government-academic-corporate-financial market interrelationships that has evolved in the United States is, literally, the envy of the world. European and Japanese governments are trying hard to undo counterproductive policies and attitudes that have hindered development of this industry. We cannot believe that the United States would voluntarily inject some of those sclerosis-producing practices into the heart of the system our competitors are striving so mightily to emulate.

The biotechnology industry is very fragile. It depends first and foremost on sources of cash to sponsor research. That money, in turn, depends upon some confidence that patents will be granted and maintained, that reasonable regulatory requirements will be imposed, and that prices will be governed by the mix of forces inherent in all competitive frameworks without imposed controls. Compromise any one of these and investment dollars will scurry to more hospitable environments.

You need not go back very far in history to see clear, concrete evidence of the fragility of the industry and its sensitivity to these components. When President Clinton and Prime Minister Blair's pronouncement about gene discoveries was misconstrued, the financial markets went into a tailspin that only subsequent clarification partially righted. When, in 1993-1994, the President's health care reform proposals contained elements of price controls, the investments in biotechnology almost

dried up. Again, it was only the lifting of that concern that rekindled opportunities for biotechnology investments; nonetheless, our SEC filings and those of my brethren contain "health-care reform and price controls" as a risk. Transform that risk into a reality and the '93-'94 investment desert for biotechnology will, by comparison, be seen as a fertile plain.

We can, therefore, make three essential points that should be considered together in formulating solutions to the problem we all recognize:

1. Small biotech companies—many of whom are years away from having commercial sales—are in the forefront of discovering, developing and bringing to market the next generation of life-saving medicines. Much of this pipeline is inevitably targeted at preventing or curing diseases that primarily affect seniors. This highlights the importance of ensuring access for seniors and helping them get drug coverage.

2. Increasing seniors' access to prescription drugs through fiscally responsible, decentralized, pluralistic private market-structures-is the best way to help seniors access drugs that are safe and affordable.

3. Efforts to implement price controls dried up investment in biotechnology research in 1993-1994 and will again this year if they progress. Allowing reimportation of drugs from Canada allows Canada's government to establish price controls and could compromise safety.

Biotechnology companies are making the next generation of medicines, especially those that treat the unmet needs of seniors.

According to a soon to be released study by Parexel, there are at least 320 biotech products in the pipeline currently. The study focuses on 57 of these products that target cancer, Parkinson's disease, Alzheimer's disease, heart disease, diabetes, chronic renal failure, osteoporosis, stroke, and osteoarthritis. The study has three main findings:

- 1) The proportion of seniors in the population is increasing.

- 2) The burden of illness in the elderly will increase.

- 3) Biotechnology will play an important role in curing and treating the diseases of the aging. The promise of biotechnology will be its new therapeutic classes and drugs that target for the individual patient.¹

As you all know, more than 8.2 million Americans are alive with cancer today and it is expected that more than 1.2 million new cases will be diagnosed in 2000. It is the second leading cause of death. According to the National Institutes of Health (NIH), more than \$107 billion are spent on the direct medical care of cancer patients and 563,000 Americans are expected to die of cancer this year.² These numbers are staggering. They represent pain and suffering on an enormous scale. Injecting the specter of price controls at one end of the development and marketing system that chokes the pipeline will increase, not decrease, the total cost of care.

Although the impact on patient well being and the total costs of care should be sufficient reasons to tread extremely cautiously when tinkering with a part of the system, it is probably worth noting the impact of investment in biotechnology research and development on the US economy. According to a soon to be released study by Ernst & Young LLP, the biotech industry has doubled in size since 1993. In 1999, the biotech industry directly employed 151,000 jobs in biotech companies and generated 287,000 more jobs to meet the supply inputs needed by the industry.³ These employment numbers are comparable to the cable/pay TV industry and the periodicals industry. When you realize that in 1998 fewer than five percent of the 1,274 biotech companies in the United States had products on the market, the opportunity for expanding dramatically the numbers of people employed in high-paying jobs is enormous even if only a small fraction of the products currently in development succeed. The industry invested \$9.9 billion in research and development to expand and improve treatment options for patients.⁴ In 1998, the industry generated a net loss of \$5.1 billion.⁵

This level of investment has been required because, inevitably, most drugs fail. A commonly-quoted statistic is that only 18% of drugs in Phase I will make it to the market. Biotechnology techniques may improve these odds, but companies and investors must be willing to take the risk of a substantial failure rate. This is not only built into the costs of developing a successful product, but also into the costs of capital. A small company, with fewer 'bets' to make, is going to have a high cost

¹ Parexel Study, Biotechnology's Impact on Diseases of the elderly: A White Paper. June 2000

² Parexel Study, Biotechnology's Impact on Diseases of the elderly: A White Paper. June 2000

³ 2000 E&Y LLP, The Economic Contributions of the Biotechnology Industry to the U.S. Economy.

⁴ 1998 E&Y Biotech annual report

⁵ 1998 E&Y Biotech annual report

of capital. Imposition or even the reasonable threat of imposition, of some price-control will drive the cost of capital to uneconomic levels.

The public's focus on drug costs reflects the importance of new therapies and people's increased need for better access to them. However, the policies that we consider putting into place today must assure people have access to the drugs currently available and to the innovative drugs of tomorrow.

This debate has highlighted the value of prescription drugs in the health care system that goes far beyond their costs. The problem is that those without insurance coverage who pay out-of-pocket do not have the benefit of volume discounts that come with coverage. That is why BIO supports coverage efforts rather than imposed discount pricing efforts that will not have their intended effect for very long.

There are approximately 100 biotech drugs and medicines on the market today. There are 320 in clinical trials, many in late stage clinical trials. Obviously this means there is much more in the pipeline than on the current market. The relief of suffering, the extension of life, and the reduced total costs of care that these drugs could mean dwarfs the savings in costs of a price-control mechanism.

Price controls, direct or indirect, will drive away investment in cutting edge, innovative research.

I have already stated the reliance of our industry on outside sources of capital, and the need for those investors, whether in public equity markets or venture capital, to envision a return on their investment commensurate with their risks. That return will not occur without bringing the drug(s) to market; and the costs of development through market approval, including failed attempts, is substantial, usually in the several hundred million dollar range. My company just raised \$18 million, a small portion of what is required, and a total that was negatively impacted by the roiling the markets experienced the Clinton-Blair announcement. We have enough money to last into 2002, but we will clearly need more. Until we are generating growing revenues, the only sources of that money are investment and licensing our products. Neither will be available if the products cannot be priced as market forces would allow to generate returns commensurate with risks. I described at the outset that preliminary results on our lead product appears to show substantial benefits in a cancer that can otherwise be associated with pain, kidney failure, anemia and a relatively short median survival. The question of whether price controls will hurt investment in research and development is far from academic.

Less than five percent of the biotech companies in the U.S. have products on the market.

The biotech industry as a whole lost \$5.1 billion.

Many companies rely on venture capitalists for funding.

A price control, whether real or perceived, will make investing in a biotech company developing innovative products too risky. Venture capitalists and investors will shift their money from biotech and invest it in industries that are less risky, time consuming; and require less corporate reinvestment in research and development.

My company and other BIO member companies are, quite obviously, worried about price control legislation. We believe that we are on the cutting edge of new life-saving therapies. Many of these therapies just would not be developed by larger, more established companies because they are not compatible with their infrastructures or capabilities or market sizes. When research investments are put at risk, lives are also at risk.

One has only to remember what happened to the biotech industry in the spring of 1994. The mere threat of price controls by President's health-care taskforce dried up biotech venture capital. The discussions of price control boards for innovative products forced 13 out of 16 companies to withdraw their initial public offerings (IPOs) of stock and their efforts to go public. Investors were not interested in investing their hard earned money into financing an industry that the federal government was considering price controlling. As an example of how seriously Wall Street took the policy discussions, companies filing for IPOs were legally required to include a statement of risk stating that the federal government was considering price controls. One of my fellow board members at BIO, Rob Chess, CEO of Inhale Therapeutics, was one of the lucky three companies in the Spring of 1994 to have a successful IPO offering and he has shared with me a provision of his risk statement to share with you as an attachment to my written testimony. Just the threat of price control legislation had to be listed as a "risk".

Of course, for smaller companies funding is even more volatile. Nasdaq's March 14 reaction to the President's restatement of four-year-old policy on gene patents is a case in point. At the close of the market the Nasdaq had dropped 200 points in one day and the biotechnology market capitalization dropped \$35 billion.

Since my company is on the stock exchange, I find it instructive to listen to the views of leaders on Wall Street and Nasdaq. This is what has been said recently on the issue of direct or indirect price controls and the impact this will have on the markets. Testifying at The Medicare Policy Briefing of the Senate Special Committee of Aging that was cosponsored by the Alliance for Aging Research, Research America!, Society for Woman's Health Research, The National Osteoporosis Foundation and the National Council on the Aging on April 13, 2000, Franklin Berger, vice president at J.P. Morgan Securities in New York (and voted top biotechnology analyst in the All-Star Survey in The Wall Street Journal), warned of the negative impact price controls would have on the biotech industry's ability to raise investor capital:

I urge anyone contemplating legislation in the drug area to be very cautious about the up-side, and be very cautious about how you attach price controls or look at how prices are managed. If it is a non-market system you will be sending a very tough message to Wall Street. And the message will not be good. It is a message I will have to take back to investors. To say this is a very potentially dangerous to returns for these companies. Research is going to take 2 to 7 years to complete, is going to require an even higher rate of potential return to justify the risk being taken.

Mary Tanner, president of Tanner and Company, New York, at the same forum followed Mr. Berger's presentation by taking his warning further and tying it to future innovation:

The pharmaceutical industry will not dissolve overnight. But, it can dissolve over a ten-year period, as was the case with the German pharmaceutical industry. As health consumers, we can't let it happen.

The question of access is brought up all the time on public health matters and price controls. It's important to remember that it matters what you have access to. We are better off spending our dollars on pharmaceutical research, which is very cost-effective, non-invasive medicine, than in

forgetting how very effective that medicine is, regardless of whether apparently high drug prices are an easy political target.⁶

Albert Berkeley, the President of Nasdaq has been very vocal against price control legislation that has been offered in the states. I'll attach his recent letters to Maine and California.

Reimportation imports other nation's price controls

From my company's point of view, importing products that have another nation's price controls attached is the same as the federal government directly setting price controls on our products. However, from the public's point of view, there are many steps in the chain of commerce between the manufacturer and the ultimate consumer. There is absolutely no guarantee, and indeed much doubt, that the prices charged by manufacturers under foreign price control regimes would be reflected in consumer-level discounts under a reimportation scheme. Moreover, it is not even clear that drugs for export are even covered under the government's price-controlling mechanisms in Canada, and only drugs labeled for export can be exported.

Mr. Chairman, my basic message is simple. The Biotechnology Industry supports improved, affordable access for seniors to drugs. About that, there should be no question. Congress, however, must deal with the drug coverage issue as a whole. Solutions need to be adequate, necessary and not destructive of the exciting breakthroughs that have been and will continue to be created from biotechnology research and development. Instituting reimportation or price controls will not get coverage to the seniors who need it. Indeed, these proposals may not even result in lower prices. However, they will hurt companies like mine and the causes they serve.

Canada

Although this is not my area of expertise, I would like to talk about Canada for a moment to raise some of these complexities in the concept of reimporting prescription drugs across the boarder.

Proponents of reimportation, pointing to differentials in pricing, advocate that reimporting products from Canada is a simple way of lowering retail prices in the United States., I am concerned however, that they have oversimplified international markets and trade as well as national sovereignty. Of course, Canada's prices are lower because of price controls (However, many generics, not price controlled in Canada, are more expensive there than they are in the U.S.). Does the U.S. really want a similar, socialized, government-run system instead of the system we have now, which is the best in the world? Moreover, there is again no guarantee that

⁶ Alliance for Aging Research Forum April, 13, 2000.

wholesalers and other middlemen in a reimportation scheme would pass along savings gained through purchases in Canada.

I find it interesting that nearly one-third of the biotech products sold in the U.S. market are not available in Canada. Some companies in this situation and other experts have stated or speculated that the reason for not selling across the border is a result of government price controls, and stringent coverage determinations—we would call it rationing in the United States—by the provinces.

Moreover, if the bills advocating reimportation pass, there are significant potential unintended consequences. The Canadian market is only 10 percent of the U.S. market. If Canadian price controls are imported to the U.S., many companies are likely to refrain from selling in Canada. This would have the effect of voiding patents in Canada destroying the intellectual property that company's worked so hard to build.

This situation also raises a major ethical dilemma. If you sell your drug in Canada and thus accept the Canadian price-controls for the US market, your investors will not receive their return-on-investment, raising your cost of capital (that you now need more as your revenues are cut) and compromising your ability to develop future drugs. If, on the other hand, you elect not to sell in Canada, thereby avoiding the impact of Canadian price controls, you are not allowing people who could benefit to have access to your drug. I do not believe that the U.S. Congress should enact legislation that poses such an ethical dilemma.

Some bills offered would require the U.S. Trade Representative (USTR) to negotiate with Canada and others to stop free-loading off the investment that U.S. companies make in research and development and end government price controls in those countries. These proposals make sense, and could potentially result in lower prices for the United States.

Reimportation could compromise confidence in drug safety and create a complex bureaucratic administrative tangle.

The Food and Drug Administration (FDA) instills consumer confidence in the safety and efficacy of drugs and biologics. We have what many perceive to be the gold standard of drug reviews and manufacturing standards. The biotechnology industry worked hard with the Congress to help modernize and streamline FDA's procedures that led to the landmark FDA Modernization Act in 1997. Never in that entire process did we suggest that anything be done to compromise FDA's standards of safety and efficacy; indeed, the biotechnology industry has supported increased funding for FDA so that it could remain abreast of scientific progress and so that it had sufficient personnel to operate effectively.

Reimportation of prescription drugs is not a new idea. In 1987, the Prescription Drug Market Act (PDMA) was passed with broad-based bipartisan support. It cleared both houses of Congress by voice vote. The act in the House was sponsored by Representative Dingell and had support from Representative Waxman, who was then chairman of the health subcommittee. The purpose of the act was to control the stream of commerce in prescription drugs to prevent the formation of a "gray market" that would stifle the FDA's attempts to protect the public from counterfeit or adulterated drugs.

The reimportation bills currently being considered by Congress, as I understand them, would undercut the goals of the PDMA. Reimportation of pharmaceuticals was opposed by Former FDA Commissioner Kessler, who pointed to the growth of Internet pharmacies as a reason that reimportation might be even more problematic today.

Today's FDA Commissioner Henney has also expressed concern that reimportation legislation would put the public at increased risk of "counterfeit or contaminated products becoming available." Perhaps more importantly, in her prepared testimony for the Appropriations Committee on March 7, Commissioner Henney noted that less than one percent of currently imported drugs are physically inspected and that "FDA's ability to physically verify the safety of domestic and imported products has eroded considerably in all product areas." One can only imagine the erosion of FDA's ability to maintain the safety of imported products if the Congress not only allowed, but actually invited, an entirely new stream of imports from around the world.

Determining whether products are "the same" for purposes of reimportation will be difficult and will inevitably create a series of regulations and definitions that will rival the tax code for complexity. In addition, many products sold overseas are not sold in the United States because of liability concerns. I am very concerned that opening our borders to imported drugs could lead to the importation of products that are not approved in the United States or are not being marketed for sale here for various reasons.

Let me say a specific word about labeling. The safety controls for prescription drugs are highly dependent on product labeling. While some of the bills attempt to solve this problem by requiring manufacturers to make U.S. labeling available for products to be reimported, this is easier legislated than done. These bills would at best establish a process of re-labeling of imported products without the strict good manufacturing practices that currently govern how products are manufactured and distributed, complete with labeling. Moreover, suppose the overseas drug is not exactly the same formulation. There would be, then, no U.S. label for the drug.

Some have argued that concerns about diversion and counterfeiting will be obviated by "strict record keeping requirements," but given the problems FDA has with current import inspections, how can we trust that products being reimported are the same products that were exported? How will we know that they have been stored properly?

In short, Mr. Chairman, while I think your goal of lower drug prices of U.S. citizens is laudable, reimportation proposals put our "gold standard" for drug regulation at risk. There is no amount of record keeping which could maintain the same kind of consumer confidence we have now when a system of reimportation is adopted. I find it hard to believe that these safety concerns can be so easily dismissed when the FDA feels it needs more resources to inspect the current level of imports. I think we need to evaluate very carefully any changes that would undercut the FDA's ability to protect the public health. I would urge you to reconsider changing a regulatory system that is the gold standard of the world.

Prescription drug coverage, especially for seniors, is the answer—not price discounting schemes or price controls.

BIO understands the need for access to drugs at reasonable prices. However, we believe that private market competition, which works to drive down cost while at the same time encouraging innovation is the winning solution. Private market mechanisms can and have effectively constrained costs for most sectors of the American public. These mechanisms should be made available to America's seniors without the undue burden on innovation that government regulation would bring. We believe that drug coverage proposals based on the private marketplace are the best solution. The BIO Board developed seven principles that have guided the industry as it participates in the Medicare coverage debate. These are:

- 1) Deliver benefits through a decentralized, pluralistic market structure that encourages meaningful competition in order to preserve patient choice, improve quality and encourage innovation.

Limit government over-regulation and utilize market-based delivery mechanisms, not direct or indirect price controls that stifle innovation.

- 2) Prioritize any federal assistance toward beneficiaries with the greatest economic and medical need in order to focus limited funds where they can have the most impact.

Make available affordable "stop loss" coverage to protect the financial security of the sickest and neediest Medicare beneficiaries.

Target subsidies for low-income beneficiaries using market-oriented, private sector approaches.

- 3) Expand beneficiaries' choices of quality health plans and benefit packages that include prescription drug coverage to ensure that all of the elements of modern healthcare are provided in a system built on the advantages of our market-based economy.

- 4) Improve patient care by promoting strong incentives for the discovery and development of innovative new prescription drugs and biologics to ensure that the new tools of biotechnology are applied as quickly as possible to create medicines for the huge unsolved medical problems of aging.

- 5) In the context of over-all market based reform, ensure drug coverage for Medicare beneficiaries does not jeopardize the financial security of the program to ensure a fiscally responsible program for the coming generations of seniors.

- 6) Avoid interfering with existing coverage and payment rules for the types of drugs and biologics currently covered by Medicare.

One major issue of access that reimportation legislation cannot address is the issue of coverage for very expensive products; price discounts just will be insufficient. BIO has proposed a so called "stop-loss" protection. We believe that this will ensure that no senior will have to worry about going bankrupt because of a chronic disease that requires long-term therapy. This is why we strongly favor comprehensive Medicare reform over a piecemeal approach.

Conclusion

Biotechnology companies believe that we have responsibilities to patients, to the public health as well as to the investors that fund our research and development. We believe strongly that any proposal in the field of health care needs to align interests of all these groups, lest we achieve some ephemeral gains while sacrificing the long-term safety and health of our people. Although hardly an expert in the field of pricing or Medicare reform, I have tried to outline directions that would lead to such an alignment of interests.

The Congress must be under no illusions about what the impact of any measure that introduces price controls, directly or indirectly, will do to investments in the biotechnology industry. They will dry up. They did in '93-94 when the specter of such measures was included in health care reform proposals. They will again. And, they will do so just at the time when exciting new developments in unraveling the human genome, in targeting therapies more specifically, provide real hope for major advances for the treatment of painful and debilitating diseases.

Thank you Mr. Chairman. I would be pleased to answer any questions you might have.

PREPARED STATEMENT OF GERALD F. MEYER

Mr. Chairman, I appreciate this opportunity to provide my views with respect to some of the Issues associated with S. 2520, the "Medicaid Equity and Drug Safety Act of 2000."

My views are predicated on my 24 years of experience at the Federal Food and Drug Administration (FDA) and six years as a consultant to the pharmaceutical, biologic, medical device and biotech industries. While at FDA I was privileged to serve as the Director of their Office of Legislative Services for 2 years, as their Associate Commissioner for Management and Operations for another 14 years, and as Deputy Director of their Center for Drug Evaluation and Research for 8 years. For the past several years I have served as a Senior Consultant with the AAC Consulting Group, Inc. in Bethesda, Maryland. This is a small consulting firm whose President and some 25 of its senior employees are former FDA officials with extensive experience in human pharmaceutical development and review, and in working with industry to achieve compliance with FDA laws and regulations in the manufacture and distribution of regulated products. A copy of my Curriculum Vitae and Bibliography is attached.

I also want to make clear at the outset that I am not appearing today on behalf of any organization or corporation, and that I am not being compensated in any way by anyone for preparing or providing this statement. Nor have I discussed this statement or the views it contains with anyone other than my colleagues at AAC Consulting Group, Inc.

I was asked to provide my views with respect to any possible safety concerns associated with the issues contained in this proposed legislation concerned with re-importation of approved drugs. It is my understanding that others will address the following economic issues:

The artificial capping of pharmaceutical prices by certain foreign governments as a condition of doing business in their markets along with the industry,

The industry's need to recover research costs of both successful and unsuccessful research efforts associated with the development of new products, and

The impact of these two factors on the industry in the context of the time required for the development of new products, the time required for the review of such products by FDA, and the impact of generic competition within the current parameters of patent protection.

I will therefore not address these issues in providing my views.

I believe there are two principal concerns with respect to the safety of products manufactured within the United States, exported to another country and then re-imported into this country for sale and/or use.

The first of these concerns the absence of any control over the storage of these products and the environmental conditions such products might be exposed to during storage outside of this country or in trans-shipment. Pharmaceuticals approved in this country have a labeled life or "expiration date." This is predicated on compliance with clearly stated conditions including refrigeration in many cases. For all products, storage is to be maintained within certain temperature and humidity specifications, and always in sanitary facilities. I can assure the Committee that FDA audits have demonstrated that these conditions are not uniformly adhered to throughout the world. Products stored or shipped out of responsible oversight and control represent a potentially significant risk to patients in this country. The Com-

mittee my wish to ask FDA for examples of some of these kinds of problems that FDA has experienced in the past.

The second safety issue would be the vulnerability of such reimported products to the substitution of counterfeit drugs. FDA has experienced shipments of products from other locations that were manufactured, and labeled and packaged to look like approved pharmaceuticals. These products may be placebo or other more easily made substitutes. They pose a risk not only because of what they are made of and the often insanitary conditions under which they are produced, but also because they mean a patient in need of a particular pharmaceutical will be taking something else other than the product for which they have a medical need. This kind of problem has occurred in the past in terms of bulk products shipped to this country, as well as smaller amounts purchased by individuals from border locations in Mexico and Canada. Again the Committee may wish to ask FDA for examples of these kinds of problems experienced in the past.

Both of these situations represent serious safety concerns in my view with the potential for injury and harm. I would earnestly hope and recommend that the Committee proceed with great care in this arena, and that they endeavor to find other ways to address their concerns about the costs of pharmaceuticals if the committee concludes that current costs are truly not justified.

I will be pleased to meet with you and/or members of your Committee and staff, or provide any further information you might believe would be helpful.

[Additional material may be found in committee files.]

STATEMENT OF THE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

The National Association of Pharmaceutical Manufacturers (NAPM) is a national, not-for-profit trade association representing manufacturers and distributors of finished, multi-source generic pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic drug industry.

NAPM commends the Committee for holding this hearing on drug issues, including drug pricing. As you know, more and more Americans are finding it difficult to afford prescription drugs and are being forced to choose between essential medicines and food.

Generic drugs provide consumers with a safe, effective, and low-cost alternative to brand name drugs. According to a 1998 Congressional Budget Office report, the substitution of generic drugs for brand name drugs saved purchasers of pharmaceuticals between \$8 billion and \$10 billion in 1994 alone.

For this reason, NAPM strongly endorses legislation introduced by Senator Tim Johnson, S. 2501, the "Generic Pharmaceutical Access and Choice for Consumers Act of 2000." S. 2501 would create a common sense preference for using FDA-approved generic drugs within federal health care programs. As a result, the bill would help American consumers and taxpayers by increasing access to low-cost, safe, and effective generic drugs.

In addition, NAPM also strongly supports inclusion of a provision that would preempt states from "second-guessing" FDA's scientific judgment that a generic drug can be substituted for its brand name counterpart. For the past several years, brand name drug companies have aggressively lobbied the states to eliminate competition by passing unwarranted restrictions on generic substitution; S. 2501 would recognize that FDA's determination is the "gold standard."

NAPM also urges the Members of this Committee to reject efforts by Schering-Plough and Columbia University to increase, directly or indirectly, patent terms on drug products. These patent extensions would provide no benefit to public health and represent billions of dollars in increased health care costs that would be paid by consumers, taxpayers, third-party payors and federal and state governments.

Schering-Plough is currently advocating legislation that would establish a process by which the Federal Court of Claims or the Patent and Trademark Office would be directed to use biased criteria to determine whether a patent extension is warranted. Under this new "process," Schering-Plough virtually would be guaranteed a three-year extension for its blockbuster drug Claritin[®], with over \$1 billion in annual U.S. sales.

Columbia University is also lobbying for a patent extension on its patent that covers a fundamental cell transformation process used in many biotech products to treat cancer, anemia, hemophilia, and other life-threatening or chronic diseases. Columbia makes non-exclusive licenses to use the process available in exchange for royalties. Because Columbia's patent on this process is due to expire in August 2000, Columbia has lobbied for this last minute, special-interest patent extension,

which would ensure them \$100 million dollars in royalty payments for each year its patent is extended.

NAPM appreciates the Committee's consideration of our testimony, including the attached letter sent to Chairman Jeffords endorsing S. 2501.

PREPARED STATEMENT OF ALAN F. HOLMER

Mr. Chairman and Members of this Committee, thank you for the opportunity to share the views of the research-based pharmaceutical industry on the subjects of this hearing, the pricing and importation of prescription medicines, and the safety risks of any repeal of existing consumer protection legislation regarding importation of medicines.

Concerns about these issues are of vital importance to us, since the 40,000 scientists in our research labs lead the way in translating advances in knowledge about biology and disease into medicines to help and heal patients. The pharmaceutical industry added 370 new medicines to the nation's medicine cabinet in the 1990s alone, medicines to fight breast cancer, osteoporosis, heart disease, stroke, schizophrenia, multiple sclerosis, prostate cancer, and many more diseases that shorten and impair lives and cause families such grief. By multiplying our investment 13-fold from \$2 billion in 1980 to \$26.4 billion this year, the pharmaceutical industry has accelerated the availability of new medicines that millions of patients had only dreamed of. And by continuing this huge private investment, we can reasonably hope to fulfill the dreams of millions more whose hopes for better health rely primarily on our continuing research.

The pharmaceutical industry is privileged to help make so many dreams come true. Yet once our companies have developed these medicines, not every patient has meaningful access to them. America's seniors in particular have disproportionate health care needs; while only 13 percent of the population, seniors account for one third of all U.S. prescription drug purchases. And, in our view, that is precisely what this hearing is about: how to help patients who need but lack access to medicines already developed, without harming patients who need but lack access to medicines not yet developed, and whose hopes for better health rest chiefly on industry's applied R&D.

The industry is committed to achieve both these goals. To help patients waiting for new medicines and hopefully cures, we have over one thousand medicines in development; we are searching for a cure for Alzheimer's, a vaccine for HIV/AIDS, and even better treatments for stroke, heart disease, multiple sclerosis, Parkinson's, cystic fibrosis, various forms of cancer, and many more. Our huge investment in R&D—\$26.4 billion this year alone—fuels our mission to help these needy patients.

But we also are concerned about the other needy patients, those whose diseases can be treated with medicines already developed if only they can afford them. That's why we support expanding private insurance drug coverage for prescription medicines for seniors and disabled Americans, using choice and competition in the private sector to ensure quality and control health care costs. We want each elderly and disabled American to have the same range of good choices among competing private-sector coverage plans that Members of Congress and other federal employees have today.

Drug Coverage Is the Right Pricing Solution

Coverage is the best way to dramatically improve seniors' access to the medicines they need because it helps them in not one, but two ways. First, coverage provides help in paying the bills for medicines. While a senior pays some costs out-of-pocket (such as any premium payments, copayments and deductible), the health plan pays the rest for covered treatments. Most seniors care about the cost to them, not the retail, wholesale or manufacturers' prices. Coverage is a pricing solution because it reduces the cost of medicines to seniors.

Second, coverage also provides access to price discounts freely negotiated in the private sector. Each big hospital, managed care provider, insurance company, or other large institutional buyer of medicines extracts the deepest discount possible from each individual drug manufacturer and from each retail pharmacy. The Administration announced on April 10 that retail pharmacy discounts alone to insured Americans average 15 percent. A recent Health Affairs article estimates that manufacturer rebates and other price discounts range from 2 percent to 35 percent, in addition to the pharmacy discounts. According to a study by the Lewin Group, discounts freely negotiated by pharmacy and manufacturers total from 30 to 39 percent. In addition, retail drug prices can vary significantly from drugstore to drugstore in the same region; according to the most recent issue of Washington Consum-

ers' Checkbook, retail drug prices in the Washington, D.C. area range by as much as 50 percent.

Some industry critics have complained that the industry seeks to avoid contributing financially to a solution for seniors by advocating expanded coverage rather than price limits. In fact, the industry would contribute substantially through the price discounts extracted by large institutional buyers from manufacturers. These discounts would be negotiated by insurers exercising their market-based negotiating leverage. As government and other studies show, prescription medicine prices are generally much lower for patients with insurance coverage than those without.

Of course, there are other ways to address drug pricing, but these approaches would harm patients waiting for new medicines and cures. Here's why.

Government Price Controls Would Fail and Would Chill Investment in R&D

First, some advocate government price controls on drug manufacturers, such as S. 731. This approach would not provide drug coverage for a single senior, and does not require the pass-through of any savings to seniors. A senior able to pay for the medicines she needs only three months a year, for example, might at best be able to pay her medicine bills for another three months under S. 731. What about the other six months? S. 731 would not give her coverage, which would help her year-round.

Even worse are proposals such as S. 2464 to import foreign government price controls and to establish lowest-price-in-the-world price ceilings on U.S. prescription medicines. This measure would prohibit a drug manufacturer from selling a prescription medicine in the U.S. at a price higher than the price charged anywhere else in the world—no matter how poor the developing country, or how severely a foreign government controls prices.

A mountain of evidence establishes that price controls do not work. And price controls in health care are positively harmful. As 535 economists from all 50 states summarized in an open letter to the President and all Members of Congress earlier this year: "In countries with price controls, health care services are severely rationed. Patients wait months and sometimes years for surgery, suffering significant harm to health, even death, as a result. Government bureaucrats, rather than doctors or patients, select treatments. Pharmaceutical innovation languishes." Attachment 1.

In summary, we urge you to oppose price controls in any form: not direct price controls, not indirect price controls, not by design, not by accident, not by stealth, not by baby steps.

Drug Coverage Is the Right Solution But Requires Private-sector Delivery

Second, some advocate providing drug coverage for seniors, but through a government-run program rather than private-sector choice and competition. We agree with the focus on coverage, but strongly oppose a government-run program. The uniform history of government-run health programs is that they resort to price controls and/or limits on access to health care in order to save money, even if they don't start out that way. For example:

Medicare did not initially involve price controls; Ways and Means Chairman Wilbur Mills urged during the floor debate in 1965: "[T]here is no intention to tell [doctors] what they may charge their patients." But now Medicare relies on a labyrinth of price controls on doctors and other health care providers. The Health Care Financing Administration employs 10,000 reimbursement codes, which in some cases it seeks to fine-tune for each of over 3,000 counties throughout the country.

The government health program for veterans did not originally involve price controls, but it does today. To boot, veterans' access to medicines is limited under a penny-wise, pound-foolish National Formulary that limits choices in six important treatment classes.

The federal/state Medicaid program requires substantial rebates. In addition, many states limit access to prescription medicines under Medicaid through monthly quotas, prior authorization requirements or other measures that too often yield adverse health outcomes. An egregious example occurred last summer in Mississippi, where Mr. Donald Ashwell couldn't pay for the \$45 antibiotic he needed because he had already exhausted the monthly limit on Medicaid prescriptions. Without the antibiotic he needed, Mr. Ashwell got sicker, was hospitalized (where the bill to Medicaid for his care was \$4,900), and died.

In short, we welcome a serious debate about the best way to expand drug coverage. We believe quality can best be ensured and costs contained through good choices among vigorously competing, risk-bearing private-sector plans. Private-sector-based coverage can achieve both goals: helping patients who need better access

today to medicines already developed, and also patients still awaiting the development of a new medicine and hopefully a cure for their disease.

Drug Importation Would Pose Health Risks and Not Prove a Pricing Solution

Other Senators advocate as a pricing solution the importation of prescription medicines, either generally or from select countries. Respectfully but strongly, we disagree. Drug import bills are simply price control bills in disguise, since they would import price-controlled drugs and thus price controls.

Yes, innovative prescription medicines can be cheaper in Canada than in the U.S., primarily because the Government of Canada controls their prices. But importing medicines from Canada would pose unacceptable health risks to Americans, and would be unlikely to afford a pricing solution in any event. Here's why.

First, the safety issue. Canada is the largest trading partner of the U.S., and most Americans think of Canada as largely like America (although as recent Canadian beer commercials underscore, not all Canadians like to think so). So, some believe that surely we can trust the safety of prescription medicines available from Canada.

But current U.S. law, the Prescription Drug Marketing Act, prohibits drug imports for a very important reason: to protect the safety of Americans. Based on a two-year House subcommittee investigation in 1986 and 1987, the Congress found:

Large amounts of drugs are being reimported to the United States. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping; and

The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

As the Act's principal architect in the House, Mr. Dingell, said:

The legislation will protect consumers from the obvious health and safety threats posed by substandard, impotent, adulterated, and counterfeit pharmaceuticals. . . . The only people who will oppose this bill are the fast buck artists and shady dealers who now profit enormously from these various nefarious practices.

Then House Energy and Commerce Health Subcommittee Chairman Henry Waxman stressed that the legislation would "provide additional assurances to American consumers that drugs they purchase will always be safe and effective." The Act was passed by voice votes in both the Senate and the House.

Over a decade later, the need for this consumer protection legislation has not abated, as the current and two prior FDA Commissioners have explained. In March 7th testimony before the Senate Appropriations/Agriculture and FDA Subcommittee, FDA Commissioner Jane Henney explained that she and her Canadian counterpart are concerned that if imports were allowed, the U.S. demand for drugs from Canada could cause Canada "to somehow be used as a front for counterfeit or contaminated products becoming available". [O]ne has to be concerned about safety issues here." While recognizing many Americans' respect for the Canadian regulatory system, the Commissioner testified that there is "still a [safety] concern". The trackability of, a pedigree of, a drug is more than in question. Where did bulk product come from? How was it manufactured? You're just putting yourself at increased risk when you don't know all of those things."

These safety concerns are shared by past FDA commissioners. Dr. David A. Kessler, now Dean of the Yale Medical School, wrote in June 1999:

In my view, the dangers of allowing re-importation of prescription drugs may be even greater today than they were in 1986. For example, with the rise of Internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years. Repealing the prohibition on re-importation of drugs would remove one of the principal statutory tools for dealing with this growing issue . . .

Attachment 2. Another former FDA Commissioner and former Dean of the University of California (San Francisco) School of Pharmacy, Jere E. Goyan, wrote:

This legislation would permit the importation and sale of prescription drugs that may have been shipped and stored under uncertain conditions, potentially weakening the medications or rendering them ineffective.

There is no provision for assuring that the drugs, once out of the manufacturer's control, are not replaced by counterfeit products that look like the original.

I respect the motivation of the members of Congress who support this legislation. . . . But the solution to this problem lies in better insurance coverage for people who need prescription drugs, not in threatening the quality of medicines for all of us.

In short, repealing the consumer protection legislation of 1988 to allow retailers and distributors to import prescription medicines would jeopardize the health and

safety of millions of Americans. The proposals to authorize such imports cannot be "fixed" to avoid such peril. Even under current law, it is all too clear that the U.S. Food and Drug Administration and U.S. Customs Service are struggling to adequately protect Americans even today against the risks of unlawfully imported medicines:

At a hearing just last Thursday, June 8, before the House Commerce Subcommittee on Oversight and Investigations, it was disclosed that the FDA has inspected only one in four (1430 of 6030) foreign drug manufacturers.

Chairman Fred Upton of the House Commerce on Oversight and Investigations noted at the hearing last Thursday that, according to the FDA, the agency has information about only 18% of the foreign drug manufacturers that ship to the U.S., and has no information on 623 importing drugs firms from China and 409 importing drug firms from India.

On the basis of information provided by the Administration, Chairman Upton concluded that "the FDA cannot assure the American people that prescription drugs are free from counterfeits and poorly made, unknown ingredients." He elaborated: "The result of a counterfeit could be that the medication will not be effective or could produce a long term disease or injury."

The World Health Organization estimates that about 5-8% of drug products shipped to the U.S. are counterfeit, unapproved or substandard. Some have estimated that 50-70% of the drugs in some developing countries are counterfeit.

"Every day people die because of counterfeit drugs," Dr. Idrissou Abdoulaye, senior official at the Ministry of Health of Benin, reported at the World Health Assembly in Geneva recently.

The Administration also testified on March 9 before the House Commerce Subcommittee on Oversight and Investigations that the spiraling growth in online pharmacy sales is overwhelming drug safety regulators and law enforcement agencies.

Betsy Durant, director of trade programs for the Customs Service, said the number of pharmaceuticals seized entering the U.S. jumped 450 percent from 1998 to 1999, an increase of 7,586 seizures.

Dean Boyd, spokesperson for the U.S. Customs Service, said about drug imports through online sales: "[Y]ou name it, it's coming in like crazy," falsely manifested as gifts, hidden in hollowed-out books (including bibles), stored in unsanitary conditions, and/or containing no dosage or other instructions. According to Boyd, Americans who buy these drugs "are really playing Russian roulette."

As the legal memorandum attached to this testimony explains (Attachment 3), the FDA procedures to ensure that prescription medicines are safe and effective for their intended use, in accordance with a doctor's prescription, are so complex, they could not possibly be replicated by Customs agents at border crossings. The "reasonable assurance" of safety and effectiveness that some proposals would purport to provide would be but a pale and dangerous imitation of FDA procedures throughout the process of human clinical trials and subsequent manufacturing, labeling, and monitoring.

Even if Canadian regulatory procedures were deemed roughly comparable to those of the U.S. FDA, new U.S. legislation repealing the 1988 consumer protection statute could not prevent transshipment of a substandard product manufactured in a poorly regulated country through Canada into the U.S. To the contrary, such repeal would be an irresistible magnet for precisely such substandard medicines being transshipped through Canadian gateways to markets in the U.S., where they would imperil the health and safety of Americans who count on the FDA to protect them against such unacceptable risks. As legal experts have concluded, "patients in this country would have no way of knowing, when they had a prescription filled, whether they were getting a genuine FDA-approved drug or an unapproved foreign version imported under [a pending legislative proposal]."

Second, in addition to the overwhelming safety issues, importing prescription medicines from Canada or anywhere else is not a pricing solution. The two-year House subcommittee investigation, based on which the Prescription Drug Marketing Act was enacted, found that any savings would go to middlemen in the U.S. and abroad, not to American consumers. Dean and former FDA Commissioner Kessler agreed last year: "Moreover, prices to ultimate consumers are generally not lowered . . . Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk."

Expanded Private-sector Drug Coverage for Seniors and Disabled Americans Is the Best Solution

Expanding private insurance coverage for seniors would afford comparable or better U.S. prices to them on average. Generic medicines generally can be obtained at lower prices in the U.S. than in Canada; generic medicines account for about 47 per-

cent of the U.S. market today (and possibly more in the near future, as 150 medicines accounting for \$50 billion in annual sales come off patent in the next five years).

Innovative medicines often cost more in the U.S. than in Canada, principally because of Canadian government price controls. But the cost differences between U.S. and Canadian medicines are often exaggerated dramatically, as Wharton Professor Patricia A. Danzon will explain at the hearing. Moreover, on average, such differences are largely offset by freely negotiated discounts available through private insurance. A Lewin Group study finds that pharmacy and manufacturer price discounts as a result of insurance coverage range from 30 to 39 percent. The Department of Health and Human Services found pharmacy discounts alone averaging 15 percent, and a recent Health Affairs article reports that manufacturer discounts range from 2 to 35 percent. Moreover, private coverage for America's seniors would more dependably help them pay for the prescription medicines they need all year round.

When making international comparisons, it is important to remember the significant impact of currency exchange rates. Rather than allowing Canadian drug prices to rise as the Canadian dollar falls (which would be natural in a free market), the Canadian government controls prices. For example, suppose you introduced a new drug throughout the world in 1991 at \$1 a pill. Assuming over the next nine years that nothing else changed except exchange rates, the same pill would cost in June 2000: \$1.22 in Japan, \$1.16 in the U.K., \$1.00 in the U.S., \$0.76 in Canada, and \$0.31 in Mexico.

This is an unfair trade practice that disadvantages American patients. We are encouraged by Senator Gorton's bill, S. 2466, which would require the Administration to address these unfair trade practices.

Conclusion

In conclusion, Mr. Chairman and Members, we recognize twin challenges: the special needs of elderly and disabled Americans today who need but lack coverage for prescription medicines, and the continuing needs of millions of patients of all ages for new medicines and hopefully cures to fight the diseases that do or will afflict them. Let's work together on ways to meet the first challenge, without doing harm to the patients whose hopes for cures rest so heavily on industry's applied R&D, or risking the safety of patients by repealing consumer protection legislation.

Thank you.

One Thing Health Care Does Not Need Is Price Controls:

An Open Letter from 535 Economists* from all 50 States on Health Care Policy Reform

Dear President Clinton and All Members of Congress:

For thousands of years, governments have tried to control prices. The universal experience has been that price controls produce shortages, black markets, reduced quality, and economic hardship.

Now, once again, programs to control health care prices are on the policy agenda. Under the guise of controlling Medicare costs and shielding the elderly from "unfair" prescription-drug prices, current proposals would restrict discounts on drug prices, cap health care spending, and limit insurance premiums. Among those adversely affected would be hospitals, members of managed care organizations, public health clinics, and government programs such as Medicaid and the Veterans Health System, which, because of their mass-buying power, are able to negotiate favorable drug prices for patients.

In countries with price controls, health care services are severely rationed. Patients wait months and sometimes years for surgery, suffering significant harm to health, even death, as a result. Government bureaucrats, rather than doctors or patients, select treatments. Pharmaceutical innovation languishes.

In recent decades, American health care firms have created hundreds of new drugs, devices, and other medical products that have saved millions of lives, not only in the United States but around the world. The best way to save millions more is to enhance the incentives to research, develop, and market new health care products. Existing price controls and other trade restrictions affecting health care goods and services should be removed in order to encourage dynamic entrepreneurship in competitive markets. The result will be lower prices, greater innovation and higher quality.

Despite claims to the contrary, price controls do not reduce medical costs. Nor do they call forth improved health care services. Instead, they produce lower-quality medical care, reduced innovation, and costly new bureaucracies to monitor compliance, adding to the burdens of health care providers already entangled in red tape. Price controls harm consumers of medical services, especially those most in need of health care services.

We urge you to oppose all forms of price controls in any health care reform.

*535 economists and other scholars from all fifty states and the District of Columbia

June 29, 1999

DAVID A. KESSLER, M.D.

The Honorable John D. Dingell
2328 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representative Dingell:

You may recall that there has been a continuing controversy about the re-importation into the United States of prescription drugs manufactured here and exported abroad (so-called "American Goods Returned"). As you know, the Prescription Drug Marketing Act of 1987 (the PDMA), Pub. L. 100-293 (Apr. 22, 1988), of which you were the principal sponsor in the House prohibits such re-importation. As the former FDA Commissioner who oversaw the implementation of many of the provisions of the PDMA, I wanted you to know of my concerns about this issue.

I believe the prohibition on re-importing exported drugs serves two critical public health purposes: (1) preventing the introduction into U.S. commerce of prescription drugs that may have been improperly stored, handled, and shipped overseas, and (2) reducing the opportunities for importation of counterfeit and unapproved prescription drugs. I know you will recall that the Energy and Commerce Committee described these purposes in its report accompanying the bill that became the PDMA:

Specifically, the existence and method of operation of a wholesale submarket, herein referred to as the "diversion market," prevents effective control over or even routine knowledge of the true sources of merchandise in a significant number of cases. As a result, pharmaceuticals which have been mislabeled, misbranded, improperly stored or shipped, have exceeded their expiration dates, or are bald counterfeits, are injected into the national distribution system for ultimate sale to consumers....

A significant volume of pharmaceuticals is being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. The ready market for reimports has also been a catalyst for the perpetration of a continuing series of frauds against American manufacturers, and has provided the cover for the importation of counterfeit pharmaceuticals in several cases. Moreover, the hazards associated with reimports have forced the Food and Drug Administration and U.S. Customs

ATTACHMENT 2

Service to spend inspectional and other resources that are solely needed in other areas.

H.R. Rep. No. 76, 100th Cong., 1st Sess. 6-7 (1987).

In 1986, the Oversight and Investigations Subcommittee of the Energy and Commerce Committee, which you chaired, described the public health and safety concerns of allowing "American Goods Returned" as follows:

[T]he clear and present danger to the public health from reimported pharmaceuticals is the threat that subpotent, superpotent, impotent or even toxic substances labeled as U.S.-produced legend drugs will enter the distribution system. The foremost danger comes from so-called "generic" drugs produced in developing countries that do not provide product patent protection for pharmaceuticals.

Uncertain Returns: The Multimillion Dollar Market in Reimported Pharmaceuticals, 99th Cong., 2nd Sess. 23 (Comm. Print 99-GG 1986). One well-publicized example involved importation of more than one million counterfeit birth control pills, complete with counterfeit packaging and labeling. *Id.*; *Dangerous Medicine: The Risk to American Consumers From Prescription Drug Diversion and Counterfeiting*, 99th Cong., 2nd Sess. 22 (Comm. Print 99-Z 1986).

In my view, the dangers of allowing re-importation of prescription drugs may be even greater today than they were in 1986. For example, with the rise of Internet pharmacies, the opportunities for illicit distribution of adulterated and counterfeit products have grown well beyond those available in prior years. Repealing the prohibition on re-importation of drugs would remove one of the principal statutory tools for dealing with this growing issue.

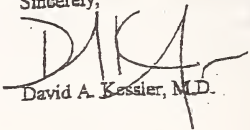
I know one argument now being made for allowing reimportation is that this would make lower priced prescription drugs available to U.S. consumers. But, your committee effectively rebutted that argument in 1986, in terms that seem to me to be equally applicable today:

Pharmaceuticals reimported by diverters displace full price sales in the wholesale market. Moreover, *prices to ultimate consumers are generally not lowered as a result of diversion. Rather, the profits go to the various middlemen, here and abroad, while consumers bear the risk.*

Uncertain Returns, *supra*, at 32 (emphasis added). See also *Dangerous Medicine*, *supra*, at 25-26 ("there is little or no significant benefit to consumers from pharmaceutical reimportation, and there are obvious costs in terms of health and safety risks and the utilization of scarce FDA resources").

I know of no changed circumstances that require either a shift in FDA policy or the passage of legislation to repeal PDMA's prohibition on re-importing drugs. Furthermore, I believe that such a repeal or change in policy would re-create the substantial public health risks PDMA was designed to eliminate. I would welcome your analysis and comments on this matter.

Sincerely,


David A. Kessler, M.D.

MEMORANDUM

Re: Medicine Equity and Drug Safety Act of 2000, S. 2520

This memorandum summarizes the substantive provisions of the Medicine Equity and Drug Safety Act of 2000, recently introduced as S. 2520 by Senator Jeffords. While the bill purports to protect the "gold standard" for safety and effectiveness applied by the FDA, it would in fact open our borders, and expose the American public, to unapproved drug products that fall well short of U.S. standards. Moreover, patients in this country would have no way of knowing, when they had a prescription filled, whether they were getting a genuine FDA-approved drug or an unapproved foreign version imported under this bill. Finally, the alleged savings offered by the bill could well prove illusory, as there is no requirement that wholesalers, pharmacists, and other middlemen pass any lower prices on to consumers.

The bill would add a new section 804 to the Federal Food, Drug, and Cosmetic Act, authorizing imports of "covered products," defined to mean any prescription drug.

Subsection (a) directs FDA to promulgate regulations that permit the importation of prescription drugs. Critically, the bill states that these regulations must permit importation "notwithstanding sections 301(d), 801(t), and 801(a)" of the existing food and drug law. Those provisions, however, set forth vital public health protections. Among other things, section 301(d) prohibits the sale of unapproved drugs, and section 801(a) authorizes FDA to keep imported drugs that are adulterated, misbranded, or unapproved out of this country's stream of commerce.

In place of these safeguards – which form the foundation for FDA drug regulation – the bill provides merely that FDA adopt regulations to provide a "reasonable assurance" of safety and effectiveness.¹ This is a far cry from the proof of safety and effectiveness required for actual FDA approval under current law. Although the bill also would allow FDA to adopt "additional safeguards," none are specified and it is apparent that this does not correspond to the full set of regulatory requirements applicable to approved drugs.

¹ Subsection (a) also provides that drugs imported by an individual comply with subsection (b) and drugs imported by a wholesaler or pharmacist comply with subsection (c). As explained below, subsection (b) does not include any requirement that the drug have been approved in the United States. While subsection (c) does refer to U.S. drug approval and related requirements, the bill does not reconcile this reference with the explicit provision in subsection (a) that importation be authorized "notwithstanding" the drug approval requirement, nor does the bill explain how FDA would enforce these requirements under subsection (c), particularly since it apparently would be stripped of its authority under section 801(a) to detain non-compliant drugs at the border.

The bill also effectively would allow other countries' approvals to override the FDA process. It specifically directs FDA to consider "the adequacy of the regulatory structure of the exporting country" in determining whether to impose additional requirements for importation. This is especially troubling because nothing in the bill would prevent transshipment of a substandard product manufactured in a poorly regulated country through a country such as Canada, a practice that would expose American consumers to the "lowest common denominator" of drug product quality throughout the world.

Subsection (b) establishes requirements for allowing importation of prescription drugs in personal baggage. Nothing in this provision requires the drug to be approved in the United States or gives any assurance of its safety, effectiveness, quality, etc. While the bill authorizes FDA to require information on the drug product, this is hardly equivalent to the actual FDA premarket approval system that Congress has determined to be essential to protecting the public against unsafe and ineffective drugs.

Subsection (c) essentially repeals the ban on reimportation of prescription drugs originally manufactured in the United States, which Congress enacted as part of the Prescription Drug Marketing Act. While a reimported product ostensibly would still be required to meet U.S. approval and related requirements, there are no specific measures in the bill that would address the concerns over counterfeiting and the like that prompted Congress to enact the ban in the first place (and this provision appears in any event to be in conflict with subsection (a) of the bill. see note 1, *supra*). The bill also appears to reflect a technical misunderstanding of existing law with respect to products manufactured overseas in registered establishments. These already can be imported if they meet U.S. requirements; there is no need to address such products in this legislation.

Bruce N. Kuhlik
Covington & Burling

MANAGING RISK FOR A MEDICARE PRESCRIPTION DRUG BENEFIT

BY DALE A. RAYMAN, F.S.A., M.A.A.A., M.H.A

The author is a healthcare actuary in Towers Perrin's national pharmacy practice.

INTRODUCTION

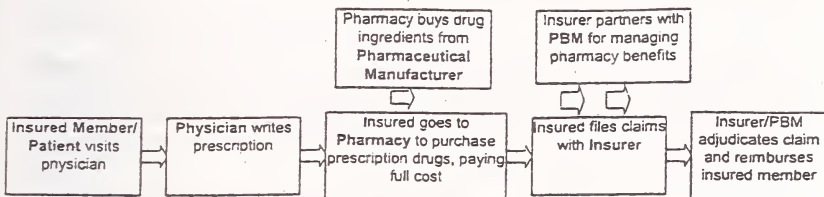
A variety of proposals have been offered in Congress to increase access to prescription drugs for Medicare enrollees. Some believe that the pharmacy issue should be addressed only as part of comprehensive Medicare reform. Others, however, believe that comprehensive Medicare reform may take years to develop and implement, and believe that many seniors may be better served by an incremental approach that addresses the lack of access to prescription drugs with more immediacy.

This paper examines one aspect of an incremental approach by demonstrating how generally accepted actuarial techniques can be used to manage the risk of a prescription drug benefit offered through insurance companies. We believe these techniques can permit insurance companies to offer seniors financial security against high drug costs, and promote access to effective health care, while avoiding unnecessary or excessive utilization that can result from adverse selection.

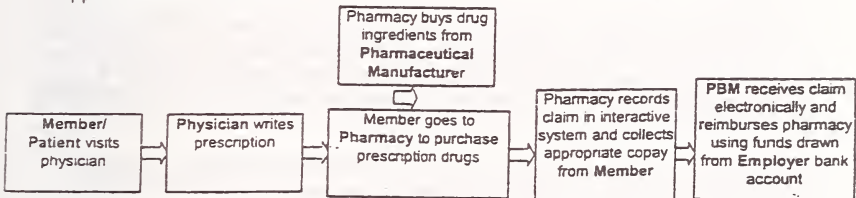
FUNDAMENTALS OF PRESCRIPTION DRUG BENEFITS

Before designing and pricing a health insurance product, an actuary usually seeks to answer several basic questions: how will health care services be approved and delivered, how much will services cost and what are the key drivers of utilization and cost. Taking a holistic approach enables the actuary to understand how the risk can be managed and thus improves the ability to predict cost and price the product appropriately (i.e., competitively yet sufficiently). This is a key step in risk management. To frame our discussion, we must understand the major stakeholders and the mechanics of delivery for a prescription drug benefit.

The diagram below shows one example of how an insured patient obtains prescription drugs. Major stakeholders, shown in bold font, include the insured member (i.e., patient), physician, pharmacist, pharmaceutical manufacturer, insurer and pharmaceutical benefit manager (PBM).



In many large companies that self-fund their benefits (i.e., do not purchase insurance), a PBM administers the pharmacy benefit directly and reimburses the pharmacy once the covered employee or dependent has paid a copayment or coinsurance. This approach is shown below:



The actuary must also understand the key cost components and what is driving increases in these costs. Key cost components for a managed pharmacy program are shown below:

$$[(\text{Ingredient Cost} + \text{Dispensing Fee} - \text{Copay} + \text{Admin Fee}) * \text{Utilization}] - \text{Rebates} + \text{Drug-related Problems} + \text{Therapeutic Failures}$$

The administrative fee paid to the PBM or insurer generally covers the cost of on-line systems, electronic edits, customer service, pharmacy network contracting and maintenance, eligibility updates, communications, physician prescribing profiling and education, and drug utilization review. (A detailed discussion of these features is beyond the scope of this paper.)

The actuary is also interested in both short- and long-term cost trends. Drug expenditures have increased between 14.4 and 18.8 percent annually over the past three years and are expected to continue this level of increase over the next couple of years. The three major components of prescription drug expenditures are: utilization, new products and elements, and price.

According to IMS Health, the main factors contributing to prescription drug spending in 1999 were non-price factors, including increased volume of prescriptions, record sales of new products, and the changing mix of available products being used. Of the 18.8 percent increase in drug expenditures (1999), 4.2 percent resulted from increased prices for existing drugs. The remaining growth was due to increased volume (10.8 percent) and new product introductions (3.8 percent).

Drug mix within a therapeutic class can change drastically as new, expensive but very effective drugs enter the market. Treatment thresholds are also lowered as these new drugs prove effective for larger groups of patients than in the past. And new drugs are being discovered to treat diseases for which no drug treatment was historically available.

With this basic understanding of prescription drug benefits, we can now begin to examine the risk management process.

FUNDAMENTALS OF RISK CONTROL

The objective of risk control is to reduce the frequency, severity or unpredictability of losses. There are numerous approaches to risk control e.g., risk avoidance, loss prevention, risk/loss reduction, risk separation, risk combination and contractual transfer of risk. In this paper we assume that most of the risk for prescription drug costs has been transferred to an insurer by purchasing insurance for a predetermined price (i.e., premium). The insurance company seeks to control or manage the risk using loss prevention and loss reduction techniques.

A key aspect of insurance is the pooling or spreading of risk. By pooling the risk for a large number of purchasers, the insurance company can improve the predictability of the average loss. By pooling risks, policyholders who have higher-than-expected losses are offset by those with lower-than-expected losses. The larger the pool, the better the predictability.

The improved predictability of large risk pools allows the actuary to establish reasonable premiums. Premium development is a critical function for insurers and involves determining a reasonable, yet sufficient, price for accepting the risk. In a competitive market, the insurer's rates must be attractive relative to the perceived value obtained by the purchaser.

In the premium development process, the actuary must consider factors that will have an impact on the risk, either positive or negative. The actuary must also estimate the probability of these factors occurring. For example, an insurer could reduce the risk of over-utilization of hospital services by implementing an inpatient pre-admission certification program. The actuary would reduce the basic premium to reflect the expected reduction in hospital utilization due to this program.

ADVERSE SELECTION

Many factors can increase the level of risk for the insurer. One of the most significant of these is adverse selection. Adverse selection is defined as the tendency of purchasers, when given a choice of benefits, to choose the plan that will produce the greatest return to them for the price. When individuals are given choice, they will gravitate to the option that provides what they perceive as the best value for the amount they spend.

Although seniors cannot precisely predict their prescription drug needs for an upcoming year, they often have a good idea of whether these needs will be high or low. For example, a senior with a complicated heart condition and diabetes is likely to need far more prescription drugs than a senior who has no chronic conditions and exercises regularly.

When an insurer increases health insurance premiums to cover adverse selection, those in good health are likely to drop coverage, thus causing the average cost to increase for remaining members. If premiums are increased once again, the healthiest of the remaining members will also drop coverage. This creates an assessment spiral whereby premiums reach such a high level that only members with the worst health status remain.

In designing an insurance product, actuaries view the benefit cost as being composed of utilization multiplied by unit cost. For example, the cost for a prescription drug benefit would be equal to the number of prescriptions filled multiplied by the average cost per prescription. In applying risk management approaches, actuaries consider the impact that each will have on utilization, unit cost or both. Adverse selection is a key factor affecting utilization.

ACTUARIAL APPROACHES FOR MANAGING RISK

This section examines several risk management approaches used by actuaries in designing health care products. These techniques are used to prevent or reduce losses and to ensure the long-term viability of the product.

Law of large numbers – A key risk management approach is the spreading of risk using risk pools. Insurers understand that the average claims cost is significantly more predictable for larger groups of covered lives than for smaller groups since there is a greater probability of obtaining an average cross-section of risks. This approach is essential for managing the risk of a Medicare prescription drug benefit. Policies that motivate a larger number of Medicare beneficiaries to choose a private insurance product will help to maintain a stable insurance market.

Premium sharing – Insurers typically require employers to contribute to the cost of group health insurance. The larger the percentage of cost contributed by the employer, the greater the participation, thereby reducing adverse selection. One of the most obvious ways to reduce adverse selection for a prescription drug benefit for Medicare beneficiaries is to have the federal government subsidize the cost for many seniors. This could be accomplished through direct payments to health insurers (e.g., similar to Medicare + Choice plans), tax credits or tax deductions. If individuals receive a substantial government subsidy (e.g., 25 percent or more of the cost), participation will be significantly greater than for a benefit that is wholly paid for by the beneficiary.

Risk-sharing – Insurers recognize that accepting 100 percent of the risk may eliminate any motivation that insured members have of helping control the risk. If, however, the insurer assumes 80 percent of the risk while members continue to pay 20 percent of the cost out of their own pockets, the member has significantly more motivation to control utilization and shop around for the best price. Risk-sharing has been used historically to control risk in health insurance and is applicable for prescription drug benefits as well. Many prescription drug plans use fixed copayments rather than percentage coinsurance so that members who must use high-cost drugs do not shoulder an inordinate burden. Copayments can also vary to provide incentives for patients to follow the most cost-effective drug therapies (e.g., generic, preferred brand, non-preferred brand).

Benefit design – Risk-sharing is one only aspect of benefit design. In addition to copayments and coinsurance, benefit provisions can also include deductibles, maximum benefit limits, internal limits, exclusions, coordination of benefits (see below), mandatory pre-certification for non-emergency high-cost care, and other cost-control incentives. The potential for adverse selection with respect to prescription drug benefits requires careful benefit design.

Individual underwriting and substandard premiums – The purpose of individual underwriting is to determine whether potential members are good or bad risks for the insurance company. Individual underwriting protects the insurer from providing coverage to a disproportionate number of unhealthy members. The worst risks are often declined coverage. Other potential members in bad health may be charged a substandard premium (i.e., a rate greater than the standard premium level). Individual underwriting can be performed using a short- or long-form questionnaire or by a physical examination by a physician.

Pre-existing condition limitations – Some health insurance policies exclude treatment for conditions that were treated during some time prior to coverage (e.g., six months). Pre-existing condition limitations generally expire after coverage has been in effect for twelve months. The Medicare program does not currently include any pre-existing condition limitations.

High Risk Pools – Individual underwriting, substandard premiums and pre-existing condition limitations are all aimed at ensuring that insurers enroll a fair cross-section of risks. An alternative approach would be to establish high-risk pools to pick up risk that exceeds certain thresholds. These pools are essentially a reinsurance mechanism and could operate in several ways. One approach, commonly used in the auto insurance industry, is to have all insurers pay a certain premium to the pool for each of their enrolled lives. The pool would then pick up excess claims for any insured. For example, the government could fund a pool to cover the risk of prescription drug claims in excess of a certain threshold per individual per year.

Eligibility requirements – Health insurers often establish eligibility provisions to reduce the potential for adverse selection. For example, employees covered in a group health plan may need to be actively at work on the effective date of their insurance. This ensures that individuals are sufficiently healthy to be engaged in gainful employment. For those not actively at work, the effective date is deferred until they return to work. Similarly, the Medicare program charges higher premiums for seniors opt out of Medicare Part B upon initial eligibility and then choose to enroll at a later date.

Closed election periods – Requiring members to enroll only during a fixed election period each year, rather than having the opportunity to change benefits at any time, reduces adverse selection. A private insurance prescription drug program for Medicare beneficiaries should limit the frequency with which enrollees can change coverage. In addition, adverse selection could also be reduced by requiring seniors who opt out of coverage to wait at least two years before re-enrolling or to pay a premium surcharge (e.g., 10 percent) during the first two years after re-enrollment.

Coordination of benefits – Insurers typically coordinate coverage with other insurance or government-sponsored coverage such that benefits are reduced if another payor is primary. Coordination of benefits (COB) provisions would continue to be an effective way for insurers to ensure that seniors are not reimbursed for more than the costs they incur. COB would also provide some cost savings for insurers.

Premium development – Careful premium development with appropriately established risk margins is another approach for controlling risk. For example, tiered rating might apply for benefits that vary significantly with age or certain other factors (e.g., whether a senior is a smoker or a non-smoker). Durational rating might be applied to reflect expected select and ultimate claims costs.

Links to other coverage – To reduce adverse selection, some health insurers have packaged together various benefits. For example, packaging vision benefits with medical benefits avoids the high adverse selection that results when only those who need glasses or contact lenses purchase vision coverage. Medicare + Choice plans are likely to combine prescription drug options with medical options to reduce adverse selection. An integrated approach to managing the health care of seniors is significantly more effective than a fragmented approach and can produce significant savings over the long term.

Risk-adjusted premiums – Risk adjusters are designed to provide higher payments to those insurers who enroll individuals who are more likely to have higher costs. For example, HCFA has proposed reimbursing Medicare + Choice plans on a risk-adjusted basis that would pay more to plans that enroll individuals with diagnoses that are projected to produce higher medical costs. Risk-adjusted premium subsidies from the federal government for prescription drug coverage would be one solution for ensuring that insurance companies that enroll a high proportion of high-cost seniors for the same average premium as competing insurers do not bear an unfair burden.

Reducing the number of options – Giving potential enrollees a choice among benefits, options or financial terms can lead to adverse selection. High benefit users will tend to choose options that provide more generous coverage whereas low benefit users will choose low-cost, less generous coverage. Insurers can reduce adverse selection by reducing the number of options. The number of prescription drug options for seniors can be limited (much like Medigap plan options) thereby reducing chances of adverse selection and facilitating comparisons among companies. Alternatively, an independent Board could be established to certify that plans meet certain minimum criteria. This would reduce the variability among plan designs and also the potential for adverse selection.

Marketing rules – Although Medicare + Choice plans are offered through the private market, the government has instituted uniform rules that level the playing field for competitors. These rules not only prevent discriminatory marketing but also ensure that all competitors have a fair chance of enrolling an average cross-section of risks. Similar rules could be considered for prescription drug plans to reduce opportunities for "cherry picking."

SOME FINAL WORDS

The actuarial design features described above are used to improve an insurer's ability to manage risk. Given the potential for adverse selection among insurers and the importance of ensuring the long-term viability of a private market Medicare prescription drug program, these techniques should be carefully considered. Good and accurate data can also help to reduce insurance costs. The impact of each approach used should be continuously monitored to measure its value.

This paper has briefly described some approaches that insurance companies can use to control risk for prescription drug benefit coverage. While designing a market-based prescription drug benefit would require careful design, there are private-market solutions that work.

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Design Elements in a Private Medicare Insurance Program for Prescription Drugs *Issue Brief*

A private prescription drug insurance program for Medicare enrollees could be viable if certain design elements are in place. The purpose of this issue brief is to identify those critical design elements and parameters. This brief is designed for an audience familiar with: 1) the Medicare program, 2) currently available prescription drug insurance options (e.g. Medicare supplemental policies and the Medicare+Choice program), as well as 3) a basic understanding of risk and the operation of the insurance industry.

The Pharmaceutical Research and Manufacturers of America has retained Stephen M. Cigich, F.S.A., M.A.A.A. of Milliman & Robertson, Inc. to prepare this issue brief. This brief is based on actuarial modeling and analysis regarding the impact of adverse selection, and reflects the author's actuarial judgment and opinion.

BACKGROUND

Private insurers would consider many issues in determining whether to participate in a prescription drug insurance program for Medicare enrollees. Issues include parameters placed on program design elements such as: the general program design (premium structure and cost sharing), pharmacy network structure, prescription drug interventions and formulary usage, pricing for future estimated utilization and cost trends, enrollment rules, existing prescription drug programs, regulatory oversight, and government subsidy mechanisms. Additionally, insurers would need to consider the possibility of future legislative changes that may have adverse effects.

Private insurers would also need to address one of the most difficult issues in designing any insurance program involving individual choice — adverse selection. This is especially true for a stand-alone prescription drug program for Medicare enrollees. However, a carefully designed program that includes the features outlined in this paper could substantially control the effects of adverse selection.

ADVERSE SELECTION - DEFINED

Adverse selection arises when potential enrollees purchase private insurance only when they believe it is in their financial interest to do so. Most people can estimate their near-term future prescription drug spending with reasonable accuracy. Barring an unforeseen change in health, a person can determine if they benefit from enrolling in a private plan based on a review of their recent prescription drug spending. This determination becomes less clear if a person must consider the need for coverage over their remaining lifetime.

Adverse selection can be measured as the increase in the per capita cost of the population electing the private plan to the per capita cost of all of those who were eligible to elect the private plan. For example, we project the average per capita drug spending, ignoring managed care discounts, in calendar year 2000 to be \$1,243 per person for all current aged enrollees. However, the distribution in average annual drug costs by quartile is striking: \$55, \$459, \$1,182, and \$3,277. If all current aged enrollees join the plan (i.e., election rate equals 100%), the average drug spending would also be \$1,243 and adverse selection would be 0%. At the other extreme, if only the 25% with the highest annual drug spending (\$3,277) enrolled, then adverse selection would be 164% $[(\$3,277 - \$1,243) / \$1,243]$.

Under a private insurance program, the initial first-year offering to all current enrollees creates the biggest potential for adverse selection impact. The fact that there are approximately 37 million people in this category magnifies the potential impact of misestimating adverse selection.

DESIGN ELEMENTS TO CONTROL ADVERSE SELECTION

Adverse selection is dynamic. The higher the average private insurance plan cost, the greater the impact of adverse selection as people with lower prescription expenses elect not to join. Consequently, program features designed to keep costs low will help in controlling adverse selection. These elements include:

Limited One-time Election Opportunity – A limited one-time election opportunity would encourage Medicare recipients to consider factors beyond the near-term in making their election decision, resulting in higher enrollment levels and reduced adverse selection.

Catastrophic Benefit Design Emphasis – A benefit design that emphasizes catastrophic protection (providing full coverage when the enrollees' calendar year prescription expenses exceed a threshold level) introduces an important protection against adverse selection. A catastrophic benefit not only protects enrollees against an uncertain future financial event; it changes their frame of reference from enrolling in a plan to obtain coverage for incidental expenses to enrolling in the plan to obtain coverage for expenses that they potentially may not be able to afford. A catastrophic benefit would necessitate up-front cost sharing features, such as annual deductibles, to help keep the premiums low.

Management Techniques – Allowing insurers to establish contractual relationships with pharmaceutical manufacturers and distribution networks would lessen product costs and thus premiums. Formularies and utilization management programs would also control expenditures.

Low-Income Subsidy – Subsidies for both premiums and deductibles for low-income enrollees would encourage their enrollment. Thus, low-income subsidies are an effective way to enroll a significant number of potential enrollees with a broad range of prescription drug costs into the program, thus reducing the level of adverse selection.

High-Risk Pool and Subsidy – A subsidized high-risk pool would allow insurers to segregate the highest users of prescription drugs from their community rate pool. By eliminating the excess cost of these individuals, the community rate level supporting all other enrollees falls. Additionally, the level of claims variance in the insurers' community rate pool falls as well. Lower claims variance provides a greater level of stability and predictability to insurance company pricing.

AN ILLUSTRATION OF A PRIVATE INSURANCE OPTION

The following is an illustration of a private insurance option for prescription drugs that incorporates these elements:

- ◆ All current Medicare enrollees (Initial Eligibles) and future Medicare enrollees (Future Eligibles) would be offered a one-time, limited opportunity to buy prescription drug insurance from private insurers on a guaranteed issue, community rated basis.
- ◆ A one-time, 6-month enrollment window would be established whereby Eligibles would be allowed to enroll on a guaranteed issue, community-rated basis. Eligibles who did not enroll during the enrollment window would apply for coverage later, but would be subject to insurance company underwriting requirements.
- ◆ Premium subsidies would be offered to individuals with incomes below a certain percentage of the poverty level. Eligibles at or below a defined income threshold would have their entire premium and any benefit deductibles paid by the government. Subsidies would be graduated so that Eligibles above a certain income level would receive no subsidy.
- ◆ High risk pools would be established to mitigate the impact the highest users of prescription drugs would have on the insurers' community rates. The government would publicly fund benefit expenditures for these high-risk individuals in excess of the community rate.
- ◆ Benefit management methods such as participating pharmacy networks, formularies, and utilization management would be permitted.
- ◆ The benefit would be designed to emphasize catastrophic protection while keeping the community premium rate reasonably low.

Addressing Issues for Private Sector Provision of Drug Insurance

Marian V. Wrobel, Ph.D., and David Kidder, Ph.D.
Abt Associates, Inc.
March, 2000

Introduction

Prescription drugs play an essential role in the treatment of disease, but providing these therapies may be costly and may impose financial burdens on the people who require them. Drug costs represent a growing share of total medical costs largely due to the growing importance of prescription medications in the treatment of disease and the increased use of these drugs.

Many individuals, including Medicare beneficiaries, would like to purchase insurance against *all* medical costs including drug costs; however, at present, fee-for-service Medicare does not include a drug benefit, and Medicare beneficiaries have only limited access to drug benefits from other sources. Three of the ten standard Medicare supplemental insurance policies include some drug coverage, but these benefits are capped at \$1,250 or \$3,000 per year and this insurance is expensive, relative both to its actuarial value and to many potential buyers' incomes. Some beneficiaries have access to drug benefits via Medicare+Choice plans, but these plans are not available in all areas and may not appeal to all beneficiaries. Some beneficiaries have employer-provided retiree health insurance that includes drug benefits. Approximately one-third of seniors report having no drug coverage at all.

There are strong arguments for policy reforms that would increase Medicare beneficiaries' access to drug insurance and that would subsidize some of the costs of that insurance. Some evidence exists that a lack of drug coverage reduces access to essential drugs among the sickest patients and results in increased use of expensive institutional services, which *are* covered by Medicare and funded publicly.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has retained Abt Associates to assess the viability of allowing the private sector to offer drug insurance for voluntary purchase by Medicare beneficiaries and enabling insurers to retain significant flexibility regarding how those benefits are designed. Private sector products could take various forms. A combination of government policies, presented below, could help to make the products affordable and to foster the success of these markets.

Advantages of Flexible, Privately-Provided Drug Benefits

Flexible, privately-provided drug benefits offer several potential advantages relative to their publicly-provided counterparts. Market competition would provide incentives for insurers to offer the best possible product at the best possible price; purchasers, voting with their pocketbooks, determine the design and generosity of their benefit. The private sector is free to adopt state-of-the-art utilization management techniques to the extent that purchasers are willing to accept them in return for the resulting reductions in premiums or cost-sharing. The private sector is also free to *negotiate* drug discounts with manufacturers; this is in contrast to government drug benefit programs which typically *mandate* drug discounts. Flexible, private benefits also allow ongoing innovation in areas such as the design of benefits, the techniques used to control costs, and special services for members; they enable Medicare beneficiaries to enjoy the same advantages as individuals with private insurance.

Adverse Selection: The Problem and Solutions

Any voluntary health insurance program faces the problem of adverse selection. At any given premium, individuals are most likely to purchase insurance if they expect their health costs (net of cost-sharing) to exceed the premium. This drives premiums higher, potentially creating a "death spiral" and provoking market collapse. Drug benefits may be particularly vulnerable to adverse selection, first because individuals can predict their expected drug costs more accurately than other components of their health expenditures, and second because the insurance policies under discussion will primarily be purchased by individuals, rather than groups. (Groups present less risk than individuals.) Also, the problem of adverse selection may discourage insurers from entering a newly opened market because the first market entrant is likely to attract the individuals with the greatest need for insurance, i.e. the highest expected costs.

Adverse selection may be exacerbated by flexible benefits. Flexible benefits further divide the market as each would-be purchaser selects the plan under which he would benefit the most. At the same time, insurers may try to structure benefits in such a way as to attract only low-cost or low-risk enrollees, that is, they will seek to avoid individuals with high expected expenditures, the very people in greatest need of drug insurance. This phenomenon is frequently referred to as "cherry-picking."

Adverse selection, however, can be substantially controlled by policies that 1) raise the total level of enrollment, 2) promote risk-neutral enrollment, and 3) keep premiums down.

Subsidies to low-income buyers or to all buyers, possibly via favorable tax treatment, raise total enrollment and, by extension, lower the risk level in the enrolled pool. Such subsidies also extend access to individuals who might otherwise find drug insurance unaffordable. In order to minimize "crowding out," subsidies should probably be available to beneficiaries

regardless of whether their drug insurance comes from a former employer, a Medicare+Choice plan, a supplemental insurance program, or another insurance product.

To promote risk-neutral enrollment, insurers might be offered some latitude for underwriting. For example, all beneficiaries might be given a six-month enrollment window with guaranteed issue, with insurers able to impose reasonable restrictions after that. (This is the existing policy for Medicare supplemental insurance, and there are similar enrollment incentives in Medicare Part B.) To encourage significant enrollment, insured individuals should probably be guaranteed the ability to renew their policies annually at community rates following initial enrollment.

A high-risk pool or assigned-risk pool could also keep premiums down and mitigate the effects of adverse selection on the drug insurance market. Reinsurance, that covers a substantial share of any individual's annual drug expenditure in excess of a very high threshold, is an alternate policy with a similar impact. Such policies also soften insurers' incentives to engage in cherry-picking.

Reasonable standards for benefits is also a way to curb cherry-picking as well as to guarantee the quality of the products available. Benefits might be regulated along such dimensions as basis of premium and a requirement to cover at least some drugs in each of a set of standard therapeutic categories while leaving insurers latitude regarding formularies, utilization review, discounts, cost-sharing, pharmacy networks, and premiums. Reasonable requirements regarding when insurers could enter and exit this market and what populations must be served by participating insurers also "level the playing field," allowing markets to develop, and ultimately serve the interests of both potential insurers and potential purchasers.

Information/Protection for Purchasers

While adverse selection is the key issue for health insurance markets, concern is often expressed that individuals do not have sufficient knowledge of the different plans available to them to make well-informed decisions. The solution to this problem would entail helping Medicare enrollees select among competing plans, by requiring insurers to submit uniform information about the benefits they offer in clear, concise language. Third parties might also offer prudent purchaser information to help beneficiaries understand tradeoffs and make informed choices. Individuals eligible for coverage under the Federal Employees Benefits Program receive this kind of assistance today. The federal Office of Personnel Management requires that plans submit certain standard information that it compiles in a plan comparison book. Similarly, Washington Consumer Checkbook (a private consumer organization) publishes a more extensive annual guide to available plans for federal workers residing in or near Washington, DC.

Conclusion

In summary, there are strong arguments for extending Medicare beneficiaries' access to drug benefits. While all options should be discussed and explored, there are some clear advantages to a system in which the private sector offers a range of different competing plans and beneficiaries are free to choose among them. Such an approach would offer Medicare beneficiaries the opportunity to select the product that best suits their needs at a competitive price. The Medicare population would benefit from the ongoing innovation taking place in the national drug benefit market. The problems of adverse selection and, to a lesser extent, information/protection for purchasers certainly pose threats to the development and success of this market but these problems can be substantially controlled via a combination of policies. Such policies might include subsidies for low-income purchasers, favorable tax treatment, risk pools or reinsurance, reasonable regulation, and some latitude for underwriting, following an open enrollment period.

Comments of Jere E. Goyan, Ph.D.

As a beneficiary of Medicare and former Commissioner of the Food and Drug Administration (FDA), I am very concerned about the proposed reimportation of prescription drugs as a means of decreasing drug costs for the elderly and disabled as proposed in S2520 the Medicine Equity and Drug Safety Act of 2000 . I recognize that drugs should be made available for the elderly and the disabled. However, I fear that the proposed solution would be substituting one risk factor for another. Now, some elderly may not be getting the drugs that are needed. Under the proposed plan, they may be getting drugs which are counterfeit, subpotent, adulterated, or otherwise dangerous.

The source of my concern is my belief that we should never underestimate the creativity of the unscrupulous. For example, it was only a few years ago that the FDA discovered that some generic drug manufactures in the United States had falsified evidence needed for approval of their drugs. Steps were taken that have probably stopped such outrageous and potentially lethal practices in the generic drug industry in America. However, a few days ago, I read in the newspapers about the seizure of condoms which had been imported from India and repackaged without disclosing their origin. Previously, the FDA had found that these condoms did not meet standards and had defects including holes. Thus problems such as this that are caused by unscrupulous activity are continuing to occur. My fear is that if this can happen to something as simple as condoms, what could happen to drugs?

Just a few weeks ago the Subcommittee on Oversight and Investigations of the Committee on Commerce of the United States House of Representatives held hearings on counterfeit bulk drugs and the threat that they pose to the American prescription drug supply. At that hearing, it was noted that the World Health Organization estimates that between 50 and 70% or the drugs sold in third world countries are counterfeit. The unscrupulous, apparently, have a thriving business.

Also at this hearing, where Dennis Baker, the FDA Associate Commissioner For Regulatory Affairs testified, it was disclosed that 75% (4,600 of 6,030) foreign drug manufacturers who have shipped Active Pharmaceutical Ingredients (APIs) to the United States have never been inspected by the FDA. (Active Pharmaceutical Ingredients are the part of the medication that is responsible for the beneficial effect.) Mr. Baker cited insufficient resources and other problems that prevent the FDA from making the appropriate inspections. The other problems include the impossibility of making unannounced inspections because of visa requirements in many countries and the impediments of language translations in others.

Although the lack of FDA supervision of imported APIs is an important issue, until now it has not posed a significant problem for the American public because there is currently a "safety net." Namely, American pharmaceutical companies are held responsible for the efficacy and safety of medicines which they produce from these APIs. The manufacturers are responsible for their own quality control, and they perform tests that ensure that the final products still meet the standards required by the FDA. In addition, American companies can be easily inspected by the FDA and are, indeed, inspected on a regular basis.

Although more can and should be done to control the quality of APIs that are imported into the United States, this problem could become less significant when compared to the potential flood of counterfeit and adulterated products that we will see if Congress passes an act to encourage reimportation of prescription drugs. If this legislation passes, health care organizations, pharmacies, and others groups will purchase these drugs but will seldom have the scientific resources or the financial motivation to perform the appropriate tests to assure safety and efficacy. The American public will no longer have the "safety net" that currently protects them from the unscrupulous.

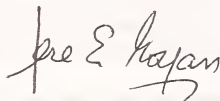
There have been proposals from the proponents of this legislation for "guaranteeing" the safety and efficacy of the reimported products. For example, in the proposed Senate bill, the FDA would be required to promulgate regulations to allow reimportation and to adopt regulations to provide "reasonable assurance" of safety and efficacy. However, the legislation does not define "reasonable assurance". The legislation also directs the FDA to consider "the adequacy of the regulatory structure of the exporting country" in determining whether or not to impose additional requirements for reimportation. It appears that the legislation would require the FDA to interpret the laws of each country and to judge their ability to provide the "reasonable assurance of safety and efficacy". However, even if the agency could interpret such laws and regulations, the FDA is already on record as stating that inspecting companies that produce and ship APIs in some countries is impossible. Therefore, although the language of the laws and regulations might be adequate, it would still be impossible to assure compliance. We would have to rely on the exporting country to provide sufficient oversight to satisfy the requirements of the United States. In many cases, this will be unlikely to occur. In addition, the potential "political" and "diplomatic" problems involved in interpreting and judging the laws and regulations of other countries would be extraordinary.

Other problems with reimportation that need to be addressed include the proper storage and handling of the drug products to avoid potential deterioration or contamination. Even if the tablet, capsule, or injectable product initially met all of the standards of the FDA, it might not do so after inappropriate storage and handling. It has been suggested that a complete "paper trail" could be required to assure that this does not happen. However, who will police the "paper trail"? How expensive will it be for the United States' Government to do so? I can not estimate the cost, but I suspect that this attempt would be very expensive and would not deter unscrupulous activity. Why not just use that money to provide drugs for Medicare beneficiaries?

The issue of drug costs for the elderly and the disabled is an important one and ways need to be found to make safe and efficacious drugs available to all patients who need them. Unfortunately, the reimportation of drugs seems to me to be an would only lower the quality of drugs in the United States and enrich the unscrupulous. The patient would be unaware that they might be at risk because of an ineffective or dangerous drug because the product would not have to be identified as reimported. The proposed bill would allow the reimportation of drugs that do not meet the requirements of the United States for safety and efficacy and would enable the unscrupulous producers and intermediaries to profit from supplying them at the expense of American patients who may use these drugs.

Last year, I wrote a letter to the editor of several newspapers across the country outlining my concerns about the original bill. I am attaching a copy of that letter to these comments. I do not believe that the new bill S2520 adequately addresses those concerns. I urge you to place the health and safety of Americans first and reject legislation that calls for the reimportation of prescription medicines.

Thank you for your consideration of my comments.

A handwritten signature in cursive script, appearing to read "Joe E. Kagan". The signature is written in dark ink on a light background.

Testimony on Prescription Drugs for Seniors under Medicare by James L. Martin, President, 60 Plus Association, June 13, 2000

Mr. Chairman,

On behalf of the 60 Plus Association, I commend you and the Senate Committee on Health, Education, Labor and Pensions for holding this hearing on a topic very important for all seniors—drug safety and pricing.

The 60 Plus Association is a national, nonpartisan senior citizens advocacy group with 500,000 members nationwide, an average of 1,000 per Congressional District. We are supported by the voluntary contributions of our members. We have never in the past nor presently receive federal grants or contracts and we have a policy that we do not seek or would we accept federal grants or contracts.

As senior citizens are living longer and healthier lives, the issue of prescription drugs becomes a major issue for their health and their budget. Years ago seniors lived into their 60s and 70s; now we have seniors living beyond those years, with an increasing population in their 80s, 90s, and even 100 years and beyond. The rational TV weather forecaster, Willard Scott, has a growing number of individuals each year from whom to select to honor on their 100th birthday.

I am not here to endorse any specific piece of legislation but mainly to highlight important principles, which should be included in any prescription drug plan.

First of all, we are very concerned with the proposal of a prescription benefit under Medicare being pushed by President Bill Clinton. The president's plan is a big government, "one size fits all" proposal that will enlarge government, promises much but delivers little, places decision-making in the hands of federal bureaucrats, and will do little to meet the diverse needs of our senior citizens. The proposal may have great political appeal in this election year but little common sense appeal to those of us who have studied it. A closer study of the proposal demonstrates that it is a bad program for senior citizens and for the American taxpayer. If we believe we have problems with financing Social Security and Medicare, let us adopt this Clinton proposal and we will have an even bigger financial disaster down the road.

We at the 60 Plus Association are pleased that a bipartisan group is working in the House and the Senate to put forward a proposal, which will really help seniors.

We believe that the essential features of any successful proposal must be a rejection of a big government role and especially one that will lead to price-fixing or price controls by the federal government. Throughout history, price controls have led inexorably to rationing. That's the major reason the Canadian health system is considered by 80 percent of seniors to be in a state of crisis. Rationing leads to long lines in emergency rooms and prompted the Canadian Minister of Health to travel to the United States a few years ago for treatment of his heart ailment.

The United States has one of the greatest pharmaceutical industries in the world. Billions are being spent to develop new drugs, many of which help our seniors live a life with less pain, a higher quality, a longer life, and assist in avoiding surgery. Price controls, especially from an entity with the power of the federal government, could bring such research progress to screeching halt. We would be killing the goose that lays the golden egg. Seniors in order to receive a lower price on a drug today would be risking the opportunity for pharmaceuticals to develop other significant drugs which may help them not only in years ahead but other seniors in future years.

Speaking of the American pharmaceutical industry, it is often used as a whipping boy. For those who participate in this approach, I would like to cite an article, which appeared in Parade magazine, September 12, 1998 authored by former House and Senate member Paul Simon. He noted that a heart scan had revealed that he was headed for a heart attack or stroke, even though he had not the usual symptoms of a heart problem such as chest pain or shortness of breath. He underwent a six-way heart bypass operation. He noted that the heart scan developed by research was responsible for him being alive today. He added "Pharmaceutical companies do an excellent job in research" and noted that they had increased their spending from \$2 billion in 1980 to \$20 billion in 1998. Senator Simon attributed his survival to the research performed by pharmaceuticals.

Seniors are a diverse group. We believe assistance should be provided to those seniors, namely low-income seniors, who need such assistance. We oppose any program that will encourage companies or other health plans to drop their current prescription drug coverage for seniors, a clear and distinct possibility under the Clinton plan. We will be risking some of the great benefits in our current health system for a real shot in the dark by a very risky federal health initiative.

And finally, we should consider the element of choice. We must give seniors this option, and not pass the entire decision-making and funding process on to federal bureaucrats. Seniors must be able to make their voices heard and their decisions known in the marketplace. Seniors will lose this voice if it stifled by a federal bureaucracy under the control of a plan, which has great political appeal (such as the president's) but dire consequences for the financial health of our country and the best interests of our senior citizens.

I urge the Senate Committee on Health, Education, Labor and Pensions to adopt a bipartisan plan, which will really help seniors, and not penalize them with new government entitlement programs of dubious benefits, costly mandates, and excessive regulations. Thank you.

Purchasing Medicines from Other Countries Is Not the Answer for Seniors

It's not very often that we see legislation introduced into the Congress that, if passed, has the potential to lessen the consumer protections that we take for granted. But a bill that is now pending before the Congress, under the name "International Prescription Drug Parity Act," would have the potential to jeopardize the quality of our prescription drug supply and the health of American patients. Three of the co-sponsors of this legislation are Senator Olympia Snowe and Representatives Tom Allen and John Baldacci.

The bill would permit pharmacists and drug wholesalers to buy prescription drugs outside the United States and sell them to unsuspecting patients. The intent of the legislation is to lower prices. After all, if a pharmacist or wholesaler can get a bargain overseas, why not?

The "why not" is obvious to me. First, the legislation is so poorly conceived that it does not even require that any savings realized by the pharmacist or wholesaler be passed along in some manner to the consumer. Thus, if this legislation is passed, it might primarily benefit only pharmacists and wholesalers.

However, that's not even the worst "why not." The worst case scenario is that this legislation would permit the importation into the U.S., and the sale to consumers, of prescription drugs that may have been shipped and stored under uncertain conditions, rendering them potentially subpotent or just plain ineffective.

As the Dean of the University of California at San Francisco School of Pharmacy for 26 years and a former Commissioner of FDA, I know that one of the guiding principles of the FDA is to take no chances with the quality of foods or medicines. Pharmaceuticals are very difficult to make. Drug companies must produce their products in facilities that are expensive to construct. They must follow very detailed manufacturing rules set forth by the FDA.

The FDA believes that such rules must to be strictly enforced so as to assure the American public that they can count on the quality of every prescription drug they receive. To a remarkable degree, the FDA has succeeded and consequently, problems with prescription drug quality are very rare in the U.S.

In 1988, Congress passed a new law, called the Prescription Drug Marketing Act, which dealt specifically with the issue of imports and exports of prescription drugs. The law prohibited the importation back into the U.S. of any drug that earlier had been exported, unless the drug remained at all times under the control of the original manufacturer.

The rationale behind this law was very clear. As the Congress said in passing it: "These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping."

The Congress went on to point out that prescription drugs are an easy target for adulterating or counterfeiting, which results in hazards to the consumer. Therefore, a sound import law is needed to protect us all. My successors at the FDA apparently share my concerns. FDA Commissioner Jane Henney, recently stated that the agency has "public health concerns" about the bill. And Dr. Henney's immediate predecessor, Dr. David Kessler, wrote to Rep. John Dingell of the House Commerce Committee that passing this bill would create "substantial public health risks."

The legislation now pending before the Congress would enable pharmacists and wholesalers to reimport drugs that had been previously shipped abroad. There is no provision in the legislation for assuring that the drugs have been held under sanitary conditions or under the right temperature. There is no provision for assuring that the drugs, since they are out of the original manufacturer's control, are not replaced by counterfeit products that look like the original. In short, there are no assurances that prescription drugs that are shipped around the world in this manner will remain of the high quality that we expect.

I respect the motivation of the Members of Congress who support this legislation. They are reading, as am I, stories about high prescription drug prices and people who are unable to pay for drugs they need. But the solution to this problem lies in better insurance coverage for people who need prescription drugs, not in threatening the quality of medicines for all of us. The "International Prescription Drug Parity Act" is simply the wrong answer to questions on how we should make the benefits of prescription medicines available to all patients.

[Whereupon, at 1:08 p.m., the committee was adjourned.]

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